UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2022
or

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

For the transition period from to

Commission file number **001-15771**

ABEONA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**83-0221517**
(State or Other Jurisdiction of incorporation or Organization	(I.R.S. Employer Identification No.)

1330 Avenue of the Americas, 33rd Floor, New York, NY 10019
(Address of principal executive offices, zip code)

(646) 813-4701
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value	ABEO	Nasdaq Capital Market

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

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

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

Large accelerated filer □
Non-accelerated filer ☒
Emerging growth company □

Accelerated filer □
Smaller reporting 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 standards provided pursuant to Section 13(a) of the Exchange Act. □

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

The number of shares outstanding of the registrants common stock as of August 1, 2022 was 5,950,382 shares.

ABEONA THERAPEUTICS INC.
Form 10-Q
For the Quarter Ended June 30, 2022

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains statements that express management's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Words such as "expects," "anticipates," "intends," "plans," "believes," "could," "would," "seeks," "estimates," and variations of such words and similar expressions, and the negatives thereof, are intended to identify such forward-looking statements. Such "forward-looking statements" speak only as of the date made and are not guarantees of future performance and involve certain risks, uncertainties, estimates, and assumptions by management that are difficult to predict. Various factors, some of which are beyond the Company's control, could cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In addition, we disclaim any obligation to update any forward-looking statements to reflect events or circumstances after the date of this report, except as may otherwise be required by the federal securities laws.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in forward-looking statements due to a number of factors. These statements include statements about: our ability to continue as a going concern; our Phase 3 clinical trial (VIITAL™) for patients with recessive dystrophic epidermolysis bullosa ("RDEB") and our beliefs relating thereto; our ability to follow patients in the Phase 3 clinical trial; our plans to continue development of AAV-based gene therapies designed to treat ophthalmic and other diseases and next-generation AAV-based gene therapies; the potential impacts of the COVID-19 pandemic on our business, operations, and financial condition; the achievement of or expected timing, progress and results of clinical development, clinical trials and potential regulatory approvals; our pipeline of product candidates; our belief that EB-101 could potentially benefit patients with RDEB; development of our novel AAV-based gene therapy platform technology; our belief in the adequacy of the clinical trial data from our VIITAL™ clinical trial, together with the data generated in the program to date, to support regulatory approvals; our dependence upon our third-party and related-party customers and vendors and their compliance with regulatory bodies; our estimates regarding expenses, future revenues, capital requirements, and needs for additional financing; our intellectual property position and our ability to obtain, maintain and enforce intellectual property protection and exclusivity for our proprietary assets; our estimates regarding the size of the potential markets for our product candidates, the strength of our commercialization strategies and our ability to serve and supply those markets; and future economic conditions or performance.

Important factors that could affect performance and cause results to differ materially from management's expectations are described in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as updated from time to time in the Company's SEC filings, including this Quarterly Report on Form 10-Q. These factors include: the impact of the COVID-19 pandemic on our business, operations (including our clinical trials), and financial condition, and on our ability to access the capital markets; our ability to successfully execute our Phase 3 clinical trial for patients with RDEB; our ability to find a potential commercialization partner for EB-101; our ability to access our existing at-the-market sale agreement; our ability to access additional financial resources and/or our financial flexibility to reduce operating expenses if required; our ability to obtain additional equity funding from current or new stockholders; our ability to out-license technology and/or other assets, deferring and/or eliminating planned expenditures, restructuring operations and/or reducing headcount, and sales of assets; the dilutive effect that raising additional funds by selling additional equity securities would have on the relative equity ownership of our existing investors, including under our existing at-the-market sale agreement; the outcome of any interactions with the U.S. Food and Drug Administration ("FDA") or other regulatory agencies relating to any of our products or product candidates; our ability to complete enrollment of patients into clinical trials to secure sufficient data to assess efficacy and safety; our ability to continue to secure and maintain regulatory designations for our product candidates; our ability to develop manufacturing capabilities compliant with current good manufacturing practices for our product candidates; our ability to manufacture cell and gene therapy products and produce an adequate product supply to support clinical trials and potentially future commercialization; the rate and degree of market acceptance of our product candidates for any indication once approved; and our ability to meet our obligations contained in license agreements to which we are party.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,133	$ 32,938
Short-term investments	13,963	12,086
Restricted cash	5,891	5,891
Accounts receivable	1,000	3,000
Other receivables	1,869	—
Prepaid expenses and other current assets	1,440	2,377
Total current assets	30,296	56,292
Property and equipment, net	7,460	12,339
Right-of-use lease assets	6,943	9,403
Licensed technology, net	—	1,384
Other assets	20	168
Total assets	$ 44,719	$ 79,586
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,738	$ 4,325
Accrued expenses	5,331	5,585
Current portion of lease liability	1,798	1,818
Current portion of payable to licensor	4,818	4,599
Deferred revenue	—	296
Total current liabilities	13,685	16,623
Payable to licensor	4,011	3,828
Other long-term liabilities	200	200
Long-term lease liabilities	6,737	7,560
Total liabilities	24,633	28,211
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value; authorized 2,000,000 shares; No shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	—	—
Common stock - $0.01 par value; authorized 200,000,000 shares; 5,870,375 and 5,888,217 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	1,467	1,472
Additional paid-in capital	703,379	705,570
Accumulated deficit	(684,726)	(655,640)
Accumulated other comprehensive loss	(34)	(27)
Total stockholders' equity	20,086	51,375
Total liabilities and stockholders' equity	$ 44,719	$ 79,586

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

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except share and per share amounts)

	For the three months ended June 30,		For the six months ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
License and other revenues	$ 1,000	$ —	$ 1,346	$ —
Expenses:				
Royalties	350	—	350	—
Research and development	6,658	8,533	17,203	16,868
General and administrative	3,460	5,182	7,684	11,444
Impairment of licensed technology	—	—	1,355	—
Impairment of right-of-use lease asset	—	—	1,561	—
Impairment of construction-in-progress	(1,460)	—	1,792	—
Total expenses	9,008	13,715	29,945	28,312
Loss from operations	(8,008)	(13,715)	(28,599)	(28,312)
Interest and other income	30	8	31	23
Interest expense	(317)	(1,500)	(518)	(2,920)
Net loss	$ (8,295)	$ (15,207)	$ (29,086)	$ (31,209)
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	(3,782)	—	(3,782)	—
Net loss attributable to Common Shareholders	$ (12,077)	$ (15,207)	$ (32,868)	$ (31,209)
Basic and diluted loss per common share	$ (2.08)	$ (3.93)	$ (5.67)	$ (8.18)
Weighted average number of common shares outstanding – basic and diluted	5,806,473	3,864,791	5,800,822	3,817,380
Other comprehensive income (loss):				
Change in unrealized gains related to available-for-sale debt securities	(4)	(4)	(7)	9
Comprehensive losses	$ (12,081)	$ (15,211)	$ (32,875)	$ (31,200)

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

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(In thousands, except share amounts)

Three months ended June 30, 2022

	Convertible Redeemable Preferred Stock									
	Series A		Series B		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at March 31, 2022	—	$ —	—	$ —	5,883,196	$ 1,471	$ 706,433	$ (676,431)	$ (30)	$ 31,443
Stock-based compensation expense	—	—	—	—	—	—	724	—	—	724
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax witholding settlement	—	—	—	—	(12,821)	(4)	4	—	—	—
Issuance of Series A and Series B Convertible Redeemable Preferred Stock, net of issuance costs	1,000,006	17,974	250,005	4,494	—	—	—	—	—	—
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	3,026	—	756	—	—	(3,782)	—	—	(3,782)
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	(1,000,006)	(21,000)	(250,005)	(5,250)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(8,295)	—	(8,295)
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	(4)	(4)
Balance at June 30, 2022	—	$ —	—	$ —	5,870,375	$ 1,467	$ 703,379	$ (684,726)	$ (34)	$ 20,086

Six months ended June 30, 2022

	Convertible Redeemable Preferred Stock									
	Series A		Series B		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	—	$ —	—	$ —	5,888,217	$ 1,472	$ 705,570	$ (655,640)	$ (27)	$ 51,375
Stock-based compensation expense	—	—	—	—	—	—	1,586	—	—	1,586
Issuance of common stock in connection with restricted share awards, net of cancellations and shares settled for tax witholding settlement	—	—	—	—	(17,842)	(5)	5	—	—	—
Issuance of Series A and Series B Convertible Redeemable Preferred Stock	1,000,006	17,974	250,005	4,494	—	—	—	—	—	—
Deemed dividends related to Series A and Series B Convertible Redeemable Preferred Stock	—	3,026	—	756	—	—	(3,782)	—	—	(3,782)
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	(1,000,006)	(21,000)	(250,005)	(5,250)	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	(29,086)	—	(29,086)
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	(7)	(7)
Balance at June 30, 2022	—	$ —	—	$ —	5,870,375	$ 1,467	$ 703,379	$ (684,726)	$ (34)	$ 20,086

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Stockholders' Equity Continued
(Unaudited)
(In thousands, except share amounts)

Three months ended June 30, 2021

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income/(Loss)	Equity
Balance at March 31, 2021	3,961,557	$ 990	$ 680,103	$ (586,706)	$ 3	$ 94,390
Stock-based compensation expense	—	—	2,428	—	—	2,428
Issuance of common stock under open market sale agreement	59,409	16	2,439	—	—	2,455
Issuance of common stock in connection with the exercise of stock options	821	—	24	—	—	24
Issuance of common stock in connection with restricted share awards, net of cancellations	28,254	7	(7)	—	—	—
Net loss	—	—	—	(15,207)	—	(15,207)
Other comprehensive income (loss)	—	—	—	—	(4)	(4)
Balance at June 30, 2021	4,050,041	$ 1,013	$ 684,987	$ (601,913)	$ (1)	$ 84,086

Six months ended June 30, 2021

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income/(Loss)	Equity
Balance at December 31, 2020	3,845,267	$ 961	$ 672,304	$ (570,704)	$ (10)	$ 102,551
Stock-based compensation expense	—	—	4,378	—	—	4,378
Issuance of common stock under open market sale agreement	122,542	32	7,634	—	—	7,666
Issuance of common stock in connection with the exercise of stock options	20,349	5	686	—	—	691
Issuance of common stock in connection with restricted share awards, net of cancellations	61,883	15	(15)	—	—	—
Net loss	—	—	—	(31,209)	—	(31,209)
Other comprehensive income (loss)	—	—	—	—	9	9
Balance at June 30, 2021	4,050,041	$ 1,013	$ 684,987	$ (601,913)	$ (1)	$ 84,086

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

ABEONA THERAPEUTICS INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	For the six months ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (29,086)	$ (31,209)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	1,584	1,641
Stock-based compensation expense	1,586	4,378
Non-cash impairment of licensed technology	1,355	—
Non-cash impairment of right-of-use lease asset	1,561	—
Non-cash impairment of construction-in-progress	1,792	—
Accretion and interest on short-term investments	(177)	266
Amortization of right-of-use lease assets	899	543
Non-cash interest	402	—
Loss on disposal of property and equipment	106	—
Change in operating assets and liabilities:		
Accounts receivable	2,000	—
Other receivables	(1,827)	—
Prepaid expenses and other current assets	937	1,387
Other assets	148	(22)
Accounts payable, accrued expenses and lease liabilities	(3,684)	(4,977)
Change in payable to licensor	(296)	2,919
Net cash used in operating activities	(22,700)	(25,074)
Cash flows from investing activities:		
Capital expenditures	(103)	(501)
Proceeds from disposal of property and equipment	1,487	—
Purchases of short-term investments	(34,442)	(15,164)
Proceeds from maturities of short-term investments	32,735	46,965
Net cash (used in) provided by investing activities	(323)	31,300
Cash flows from financing activities:		
Proceeds from open market sales of common stock	—	7,666
Proceeds from exercise of stock options	—	691
Proceeds from issuance of Series A and Series B Convertible Redeemable Preferred Stock, net of issuance costs	22,468	—
Redemption of Series A and Series B Convertible Redeemable Preferred Stock	(26,250)	—
Net cash (used in) provided by financing activities	(3,782)	8,357
Net increase (decrease) in cash, cash equivalents and restricted cash	(26,805)	14,583
Cash, cash equivalents and restricted cash at beginning of period	38,829	13,571
Cash, cash equivalents and restricted cash at end of period	$ 12,024	$ 28,154
Supplemental cash flow information:		
Cash and cash equivalents	$ 6,133	$ 27,179
Restricted cash	5,891	975
Total cash, cash equivalents and restricted cash	$ 12,024	$ 28,154

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

NOTE 1 – NATURE OF OPERATIONS AND SIGNIFICANT ACCOUNTING POLICIES

Background

Abeona Therapeutics Inc. (together with the Company's subsidiaries, "Abeona" or the "Company"), a Delaware corporation, is a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening rare genetic diseases. The Company's lead clinical program is EB-101, an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa ("RDEB"), which is currently in the pivotal Phase 3 VIITAL™ clinical trial. The Company's development portfolio also features AAV-based gene therapies designed to treat ophthalmic and other diseases and next-generation AAV-based gene therapies using the novel AIM™ capsid platform that the Company has exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

Reverse Stock Split

On June 30, 2022, the Company filed a Certificate of Amendment to the Company's Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Amendment"), to effectuate a reverse stock split of the Company's outstanding common stock, par value $0.01 per share ("Common Stock"), at an exchange ratio of 25-to-1 (the "Reverse Stock Split"). The Reverse Stock Split was effective on July 1, 2022. The number of authorized shares of Common Stock immediately after the Reverse Stock Split ("New Common Stock") remains at 200,000,000 shares. All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated.

As a result of the Reverse Stock Split, every 25 shares of Common Stock outstanding immediately prior to the effectiveness of the Reverse Stock Split were combined and converted into one share of New Common Stock without any change in the par value per share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would otherwise be entitled to a fraction of one share of New Common Stock as a result of the Reverse Stock Split instead received an amount in cash equal to such fraction multiplied by the closing sale price of Common Stock on the Nasdaq Capital Market on July 1, 2022, as adjusted for the Reverse Stock Split.

Proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options, restricted stock and warrants outstanding at July 1, 2022, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, restricted stock and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants. In addition, the number of shares reserved for issuance under the Company's 2015 Equity Incentive Plan were reduced proportionately.

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). All intercompany balances and transactions have been eliminated in consolidation. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made. These unaudited interim condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period. Certain information that is normally required by U.S. GAAP has been condensed or omitted in accordance with rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The December 31, 2021 condensed consolidated balance sheet was derived from the audited statements, but does not include all disclosures required by U.S. GAAP.

Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 31, 2022.

Uses and Sources of Liquidity

The unaudited interim condensed consolidated financial statements have been prepared on the going concern basis, which assumes the Company will have sufficient cash to pay its operating expenses, as and when they become payable, for a period of at least 12 months from the date the financial report is issued.

As of June 30, 2022, the Company had cash, cash equivalents, restricted cash and short-term investments of $26.0 million. For the six months ended June 30, 2022, the Company had cash outflows from operations of $22.7 million. The Company has not generated significant revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, could be sustained on a continuing basis. In addition, development activities, clinical and nonclinical testing, and commercialization of the Company's product candidates will require significant additional financing.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, risks related to the successful discovery and development of product candidates, obtaining the necessary regulatory approval to market the Company's product candidates, raising additional capital to continue to fund the Company's operations, development of competing drugs and therapies, protection of proprietary technology and market acceptance of the Company's products. As a result of these and other risks and the related uncertainties, there can be no assurance of the Company's future success.

The Company believes that its current cash and cash equivalents, restricted cash and short-term investments are only sufficient to fund its operating expenses into the second quarter of 2023. However, in order to further advance development and seek potential regulatory approval of the Company's investigational EB-101 product for RDEB or to advance any of the Company's preclinical AAV ophthalmology assets, the Company would need to secure additional funds through equity or debt offerings, potential upfront payments from potential commercial partners, potential sale of a priority review voucher, or other potential sources. The Company cannot be certain that additional funding will be available on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about the Company's ability to continue as a going concern within one year from the date of these interim condensed consolidated financial statements. The interim condensed consolidated financial statements do not contain any adjustments that might result from the resolution of any of the above uncertainty.

Use of Estimates

The preparation of unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the unaudited interim condensed consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Actual results could differ from these estimates and assumptions.

Summary of Significant Accounting Policies

There have been no new or material changes to the significant accounting policies discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 that are of significance, or potential significance, to the Company, other than the adoption of accounting pronouncements below.

Reclassifications

Certain comparative figures have been reclassified to conform to the current year presentation. The Company reclassified depreciation and amortization costs of $0.8 million and $16,000 to research and development and general and administrative expenses, respectively, on the condensed consolidated statements of operations and comprehensive loss during the three months ended June 30, 2021. The Company reclassified depreciation and amortization costs of $1.6 million and $32,000 to research and development and general and administrative expenses, respectively, on the condensed consolidated statements of operations and comprehensive loss during the six months ended June 30, 2021. The Company also reclassified certain rent expenses of $0.3 million and $0.6 million from general and administrative to research and development expenses on the condensed consolidated statements of operations and comprehensive loss during the three and six months ended June 30, 2021, respectively. Additionally, the Company also reclassified $5.0 million of restricted cash from prepaid expenses, other current assets and restricted cash and $0.9 million of restricted cash from other assets and restricted cash to restricted cash on the condensed consolidated balance sheets as of December 31, 2021.

Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock. The Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive. Potential dilutive securities result from outstanding restricted stock, stock options, and stock purchase warrants.

The following table sets forth the potential securities that could potentially dilute basic income/(loss) per share in the future that were not included in the computation of diluted net loss per share because to do so would have been anti-dilutive for the periods presented:

	For the three and six months ended June 30,	
	2022	2021
Stock options	265,411	309,059
Restricted stock	61,108	128,725
Warrants	1,788,000	—
Total	2,114,519	437,784

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, "Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies the accounting for convertible instruments by eliminating the requirement to separately account for embedded conversion features as an equity component in certain circumstances. A convertible debt instrument will be reported as a single liability instrument with no separate accounting for an embedded conversion feature unless separate accounting is required for an embedded conversion feature as a derivative or under the substantial premium model. The ASU simplifies the diluted earnings per share calculation by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. Further, the ASU requires enhanced disclosures about convertible instruments. The Company adopted ASU 2020-06 as of January 1, 2022 and there was no material impact on the condensed consolidated financial statements upon adoption.

NOTE 2 – SHORT-TERM INVESTMENTS

The following table provides a summary of the short-term investments (in thousands):

	June 30, 2022			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments				
U.S. treasury securities	$ 13,970	—	(7)	$ 13,963
Total available-for-sale, short-term investments	$ 13,970	—	(7)	$ 13,963

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Available-for-sale, short-term investments				
U.S. treasury securities	$ 12,077	9	—	$ 12,086
Total available-for-sale, short-term investments	$ 12,077	9	—	$ 12,086

As of June 30, 2022, the available-for-sale securities classified as short-term investments mature in one year or less. Unrealized losses on available-for-sale securities as of June 30, 2022 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. None of the short-term investments have been in a continuous unrealized loss position for more than 12 months. Accordingly, no other-than-temporary impairment was recorded for the three or six months ended June 30, 2022.

There were no significant realized gains or losses recognized on the sale or maturity of available-for-sale investments for the three or six months ended June 30, 2022 or 2021.

NOTE 3 – PROPERTY AND EQUIPMENT, NET

Property and equipment are stated at cost and depreciated or amortized using the straight-line method based on useful lives as follows (in thousands):

	Useful lives (years)	June 30, 2022	December 31, 2021
Laboratory equipment	5	$ 8,619	$ 9,081
Furniture, software and office equipment	3 to 5	1,909	1,896
Leasehold improvements	Shorter of remaining lease term or useful life	8,603	8,603
Construction-in-progress		—	3,219
Subtotal		19,131	22,799
Less: accumulated depreciation		(11,671)	(10,460)
Total property and equipment, net		$ 7,460	$ 12,339

Depreciation expense was $0.8 million for the three months ended June 30, 2022 and 2021, respectively, and $1.6 million for the six months ended June 30, 2022 and 2021, respectively. During the three and six months ended June 30, 2022, the Company incurred a loss on disposal of equipment of $0.1 million which is reflected in general and administrative expenses in the condensed consolidated statements of operations and comprehensive loss.

On March 31, 2022, the Company announced that it was pursuing a strategic partner to take over development activities of ABO-102 and that it was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the construction-in-progress that was dedicated to the ABO-101 and ABO-102 programs had no future value, and thus, the Company recorded an impairment charge of $3.3 million for the three months ended March 31, 2022. During the three months ended June 30, 2022, the Company received a $1.5 million refund from a vendor related to the proposed construction-in-progress and recorded a reduction of the impairment charge of $1.5 million. For the six months ended June 30, 2022, the net impairment charge recorded was $1.8 million.

NOTE 4 – LICENSED TECHNOLOGY

On May 15, 2015, the Company acquired Abeona Therapeutics LLC, which had an exclusive license through Nationwide Children's Hospital to the AB-101 and AB-102 patent portfolios for developing treatments for patients with Sanfilippo Syndrome Type A and Type B. The license is amortized over the life of the license of 20 years. On March 31, 2022, the Company announced that it was pursuing a strategic partner to take over development activities of ABO-102 and that it was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the remaining value of the licensed technology had no future value and thus, recorded an impairment charge of nil and $1.4 million for the three and six months ended June 30, 2022, respectively.

The following table provides a summary of licensed technology (in thousands):

	June 30, 2022	December 31, 2021
Licensed technology	$ 2,156	$ 2,156
Less accumulated amortization	(801)	(772)
Less impairment charge	(1,355)	—
Total licensed technology, net	$ —	$ 1,384

Amortization expense on licensed technology was nil and $29,000 for the three months ended June 30, 2022 and 2021, respectively and $29,000 and $44,000 for the six months ended June 30, 2022 and 2021, respectively.

NOTE 5 – SETTLEMENT LIABILITY

On November 12, 2021, the Company entered into a settlement agreement ("Settlement Agreement") with the Company's prior licensor REGENXBIO Inc. ("REGENXBIO") to resolve all existing disputes between the parties. In accordance with the Settlement Agreement, the Company agreed to pay REGENXBIO a total of $30.0 million, payable as follows: (1) $20.0 million paid in November 2021 after execution of the Settlement Agreement, (2) $5.0 million on the first anniversary of the effective date of the Settlement Agreement, and (3) $5.0 million upon the earlier of (i) the third anniversary of the effective date of the Settlement Agreement or (ii) the closing of a Strategic Transaction, as defined in the Settlement Agreement.

As of June 30, 2022, the Company recorded the payables due to REGENXBIO in the condensed consolidated balance sheets based on the present value of the remaining payments due to REGENXBIO under the Settlement Agreement using an interest rate of 9.6%. The current portion of the payable due in November 2022 is $4.8 million and the long-term portion due in November 2024 is $4.0 million as of June 30, 2022. As of June 30, 2022, the Company recorded $5.0 million of restricted cash in the condensed consolidated balance sheet that serves as collateral for the payment owed to REGENXBIO in November 2022.

NOTE 6 – FAIR VALUE MEASUREMENTS

The Company calculates the fair value of the Company's assets and liabilities that qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of accounts receivable, prepaid expenses and other current assets, other assets, accounts payable, accrued expenses, payables to licensor and deferred revenue approximate their carrying amounts due to the relatively short maturity of these instruments.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 - Quoted prices in active markets for identical assets or liabilities.
- Level 2 - Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

The Company has segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

The following table provides a summary of financial assets measured at fair value on a recurring and non-recurring basis as of June 30, 2022 and December 31, 2021 (in thousands):

Description	Fair Value at June 30, 2022	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents				
Money market fund	$ 2,860	$ 2,860	$ —	$ —
Short-term investments				
U.S. treasury securities	13,963	—	13,963	—
Total assets measured at fair value	$ 16,823	$ 2,860	$ 13,963	$ —

Description	Fair Value at December 31, 2021	Level 1	Level 2	Level 3
Recurring Assets:				
Cash equivalents				
Money market fund	$ 28,590	$ 28,590	$ —	$ —
Short-term investments				
U.S. treasury securities	12,086	—	12,086	—
Total recurring assets	40,676	28,590	12,086	—
Non-recurring Assets				
Licensed technology, net	$ 1,384	$ —	$ —	$ 1,384
Total assets measured at fair value	$ 42,060	$ 28,590	$ 12,086	$ 1,384

NOTE 7 – ACCRUED EXPENSES

The following table provides a summary of the components of accrued expenses (in thousands):

	June 30, 2022	December 31, 2021
Accrued employee compensation	$ 1,855	$ 1,794
Accrued contracted services and other	3,476	3,091
Accrued sublicense fee owed to licensor	—	700
Total accrued expenses	$ 5,331	$ 5,585

NOTE 8 – LEASES

The Company leases space under operating leases for manufacturing and laboratory facilities in Cleveland, Ohio, as well as administrative offices in New York, New York. The Company also leases office space in Madrid, Spain as well as certain office equipment under operating leases, which have a non-cancelable lease term of less than one year and, therefore, the Company has elected the practical expedient to exclude these short-term leases from the Company's right-of-use assets and lease liabilities.

On March 31, 2022, the Company announced that they were pursuing a strategic partner to take over development activities of ABO-102 and that the Company was discontinuing development of ABO-101. As a result of this shift in priorities, the Company determined the portion of the lease which was dedicated to the future facility for the ABO-101 and ABO-102 programs, had no future value and thus, the Company recorded an impairment charge of nil and $1.6 million for the three and six months ended June 30, 2022, respectively.

The following table provides a summary of the components of lease costs and rent (in thousands):

	For the three months ended June 30,		For the six months ended June 30,	
	2022	2021	2022	2021
Operating lease cost	$ 461	$ 434	$ 933	$ 868
Variable lease cost	116	104	212	239
Short-term lease cost	20	5	41	10
Total operating lease costs	$ 597	$ 543	$ 1,186	$ 1,117

Maturities of the Company's operating lease liabilities, which do not include short-term leases, as of June 30, 2022 are as follows:

Maturity of lease liabilities:	*(in thousands)*
Remainder of 2022	$ 892
2023	1,835
2024	1,877
2025	1,547
2026	871
Thereafter	3,663
Total undiscounted operating lease payments	10,685
Less: imputed interest	2,150
Present value of operating lease liabilities	$ 8,535

The weighted-average remaining term of the Company's operating leases was 82 months and the weighted-average discount rate used to measure the present value of the Company's operating lease liabilities was 7.2% as of June 30, 2022.

NOTE 9 – STOCK-BASED COMPENSATION

The Company has two stock-based compensation plans: (1) Abeona Therapeutics Inc. 2015 Equity Incentive Plan (the "2015 Incentive Plan"), which was approved by stockholders on May 7, 2015 and last amended on May 20, 2020 and (2) Abeona Therapeutics Inc. 2005 Equity Incentive Plan (the "2005 Incentive Plan"), under which no further grants can be made.

The following table summarizes stock-based compensation expense for the three and six months ended June 30, 2022 and 2021 (in thousands):

	For the three months ended June 30,		For the six months ended June 30	
	2022	2021	2022	2021
Research and development	$ 540	$ 1,092	$ 556	$ 2,247
General and administrative	184	1,336	1,030	2,131
Total stock-based compensation expense	$ 724	$ 2,428	$ 1,586	$ 4,378

Stock Options*:* The Company estimates the fair value of each option award on the date of grant using the Black-Scholes option valuation model. The Company then recognize the grant date fair value of each option as compensation expense ratably using the straight-line attribution method over the service period (generally the vesting period). The Black-Scholes model incorporates the following assumptions:

- Expected volatility – the Company estimates the volatility of the share price at the date of grant using a "look-back" period which coincides with the expected term, defined below. The Company believes using a "look-back" period which coincides with the expected term is the most appropriate measure for determining expected volatility.
- Expected term – the Company estimates the expected term using the "simplified" method, as outlined in Staff Accounting Bulletin No. 107, "Share-Based Payment."
- Risk-free interest rate – the Company estimates the risk-free interest rate using the U.S. Treasury yield curve for periods equal to the expected term of the options in effect at the time of grant.
- Dividends – the Company uses an expected dividend yield of zero because there have been no declared or paid a cash dividend, nor are there any plans to declare a dividend.

The Company estimated the fair value of stock options granted in the periods presented utilizing a Black-Scholes option-valuation model utilizing the following assumptions:

	For the six months ended June 30,	
	2022	2021
Expected volatility	95.1% - 96.0%	98.9% - 99.8%
Expected term	6.07 - 6.08 years	5.25 - 6.08 years
Risk-free interest rate	1.7% - 3.3%	0.9% - 1.2%
Expected dividend yield	—	—

The following table summarizes stock option activity for the 2015 Incentive Plan during the six months ended June 30, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	314,194	$ 38.48	7.63	$ —
Granted	7,760	$ 5.30	—	$ —
Cancelled/forfeited	(56,556)	$ 35.31	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at June 30, 2022	265,398	$ 38.18	6.69	$ 5
Exercisable	148,066	$ 38.28	5.02	$ —
Unvested	117,332	$ 38.05	8.81	$ 5

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. As of June 30, 2022, the total compensation cost related to non-vested option awards not yet recognized was approximately $4.0 million with a weighted average remaining vesting period of 2.5 years.

The following table summarizes stock option activity for the 2005 Incentive Plan during the six months ended June 30, 2022:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	3,200	$ 32.00	1.80	$ —
Cancelled/forfeited	—	$ —	—	$ —
Exercised	—	$ —	—	$ —
Outstanding at June 30, 2022	3,200	$ 32.00	1.29	$ —
Exercisable	3,200	$ 32.00	1.29	$ —
Unvested	—	$ —	—	$ —

Restricted Stock:

The following table summarizes restricted stock award activity during the six months ended June 30, 2022:

	Number of Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	97,260	$ 46.59
Granted	12,680	$ 6.29
Cancelled/forfeited	(27,161)	$ 39.38
Vested	(21,671)	$ 53.07
Outstanding at June 30, 2022	61,108	$ 39.14

As of June 30, 2022, there was approximately $2.1 million of total unrecognized compensation expense related to unvested restricted stock awards, which is expected to be recognized over a weighted average vesting period of 2.6 years.

NOTE 10 – EQUITY

Series A and B Convertible Redeemable Preferred Stock

On May 2, 2022, the Company consummated an offering with certain institutional investors for the private placement of 1,000,006 shares of the Company's Series A Convertible Redeemable Preferred Stock (the "Series A Preferred Stock") and 250,005 shares of the Company's Series B Convertible Redeemable Preferred Stock (the "Series B Preferred Stock" and together with the Series A Preferred Stock, the "Preferred Stock"). The shares, which have since been redeemed in accordance with their terms described below, and are thus no longer outstanding as of June 30, 2022, had an aggregated stated value of $25.0 million. Each share of the Preferred Stock had a purchase price of $19.00, representing an original issue discount of 5% of the stated value. In connection with this offering, the Company had net proceeds of $22.5 million and recognized a deemed dividend of $3.8 million. In connection with this transaction, the Company placed $26.3 million into an escrow account for any future redemption which consisted of the gross proceeds of $25.0 million and the redemption value of $1.3 million.

The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by the Company, into shares of Common Stock at a conversion price of $11.25 per share. The holders of the Series A Preferred Stock and Series B Preferred Stock had the right to require the Company to redeem their shares of preferred stock for cash at 105% of the stated value of such shares commencing after the earlier of the receipt of stockholder approval of an amendment to the Company's Restated Certificate of Incorporation to effect a reverse stock split and 60 days after the closing of the issuances of the Series A Preferred Stock and Series B Preferred Stock and until 90 days after such closing. The Company had the option to redeem the Series A Preferred Stock for cash at 105% of the stated value commencing after the 90th day following the closing of the issuance of the Series A Preferred Stock, subject to the holders' rights to convert the shares prior to such redemption. As a result, the Preferred Stock was recorded separately from stockholders' equity because it was redeemable upon the occurrence of redemption events that were considered not solely withing the Company's control. As such, during the three months ended June 30, 2022, the Company recognized approximately $3.8 million in deemed dividends related to the Preferred Stock in the condensed consolidated statements of operations and comprehensive loss and the condensed consolidated statements of changes in stockholders' equity.

On June 17, 2022, the holders of all 1,000,006 shares of Series A Preferred Stock and 250,005 shares of Series B Preferred Stock exercised their right to cause the Company to redeem all such shares for $26.3 million, which represented a price equal to 105% of the stated value. The redemption of these shares was paid out of the escrow account noted above.

Common Stock and Warrants

Reverse Stock Split

Effective July 1, 2022, the Company's stock underwent a 25:1 Reverse Stock Split. The number of authorized shares of Common Stock immediately after the Reverse Stock Split ("New Common Stock") remained at 200,000,000 shares.

Public Offerings

On December 21, 2021, the Company closed an underwritten public offering of 1,788,000 post-split shares of common stock at a public offering price of $9.75 post-split per share and stock purchase warrants to purchase 1,788,000 post-split shares of common stock at an exercise price of $9.75 post-split. The net proceeds to the Company were approximately $16.0 million, after deducting $1.5 million of underwriting discounts and commissions and estimated offering expenses payable by the Company.

As of June 30, 2022, there were 1,788,000 post-split stock purchase warrants outstanding. These stock purchase warrants expire on December 21, 2026. During such time as each warrant is outstanding, the holder of the warrant is entitled to participate in any dividends or other distribution of assets to holders of shares of common stock. There was no warrant activity during the three or six months ended June 30, 2022.

NOTE 11 – LICENSE AGREEMENT

On May 16, 2022, the Company and Ultragenyx Pharmaceutical Inc. ("Ultragenyx") entered into an exclusive license agreement (the "License Agreement") for AAV gene therapy ABO-102 for the treatment of Sanfilippo syndrome type A (MPS IIIA) ("ABO-102"). Under the License Agreement, Ultragenyx will assume responsibility for the ABO-102 program from the Company, with the exclusive right to develop, manufacture, and commercialize ABO-102 worldwide. Also pursuant to the License Agreement, following regulatory approval, the Company is eligible to receive tiered royalties from mid-single-digit up to 10% on net sales and up to $30.0 million in commercial milestone payments. Both forms of consideration comprise the transaction price to which the Company expects to be entitled in exchange for transferring the related intellectual property and certain, contractually-specified transition services to Ultragenyx. The sales-based royalty and milestone payments are subject to the royalty recognition constraint. As such, these fees are not recognized as revenue until the later of: (a) the occurrence of the subsequent sale, and (b) the performance obligation to which they relate has been satisfied.

Additionally, pursuant to the License Agreement, Ultragenyx will reimburse the Company for certain development and transition costs actually incurred by the Company. These costs are passed through to Ultragenyx without mark-up. The Company has determined that these costs are not incurred for the purpose of satisfying any performance obligation under the License Agreement. Accordingly, the reimbursement of these costs is recognized as a reduction of research and development costs. Such amounts due to the Company from Ultragenyx under the License Agreement of $1.8 million are recorded as a component of other receivables in the condensed consolidated balance sheets as of June 30, 2022.

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

You should read the following discussion and analysis together with our unaudited condensed consolidated financial statements and accompanying notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 (the "Annual Report"). This discussion and analysis contains forward-looking statements, which involve risks and uncertainties. As a result of many factors, such as those described under "Forward-Looking Statements," "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

OVERVIEW

Abeona Therapeutics Inc. ("we," "our," "Abeona" or the "Company") is a clinical-stage biopharmaceutical company developing cell and gene therapies for life-threatening rare genetic diseases. Our lead clinical program is EB-101, an autologous, gene-corrected cell therapy for recessive dystrophic epidermolysis bullosa ("RDEB"), which is currently in the pivotal Phase 3 VIITAL™ clinical trial.

Our development portfolio also features AAV-based gene therapies designed to treat ophthalmic and other diseases and next-generation AAV-based gene therapies using the novel AIM™ capsid platform that we have exclusively licensed from the University of North Carolina at Chapel Hill, and internal AAV vector research programs.

RECENT DEVELOPMENTS

EB-101 (Autologous, Gene-Corrected Cell Therapy) for RDEB

We achieved target enrollment in the first quarter of 2022 for our pivotal Phase 3 VIITAL™ study for our investigational product for RDEB, EB-101. We anticipate topline data readout in the late third quarter or early fourth quarter of 2022. We are focusing our research and development resources on the VIITAL™ readout while actively pursuing a potential commercialization partner. We are optimistic about EB-101's potential based on updated Phase 1/2a results presented at various medical congresses.

We have continued to prepare our current Good Manufacturing Practices ("cGMP") commercial facility in Cleveland, Ohio for manufacturing EB-101 drug product to support our planned Biologics License Application ("BLA") filing to the U.S. Food and Drug Administration ("FDA"). EB-101 study drug product for all our VIITAL™ study participants has been manufactured at our Cleveland facility and we have now completed submission of Module 3 for Chemistry, Manufacturing and Controls ("CMC") describing the in-house production of both retroviral vector and the final drug product to the Investigational New Drug Application ("IND"). Based on feedback from the FDA, we believe that we have alignment with the FDA on the CMC requirements for EB-101, including characterization and validation plans

Ultragenyx License Agreement

On May 16, 2022, we entered into an exclusive license agreement (the "License Agreement") with Ultragenyx Pharmaceutical Inc. ("Ultragenyx") for our investigational AAV gene therapy ABO-102 for the treatment of Sanfilippo syndrome type A ("MPS IIIA") ("ABO-102"). Under the License Agreement, Ultragenyx will assume responsibility for the ABO-102 program from us, with the exclusive right to develop, manufacture, and commercialize ABO-102 worldwide. Also pursuant to the License Agreement, following regulatory approval, we are eligible to receive tiered royalties from mid-single-digit up to 10% on net sales and up to $30.0 million in commercial milestone payments.

Preclinical Pipeline

While our lead clinical program is currently focused on an ultra-rare indication, we intend to address larger areas of unmet medical need in the future, and our preclinical programs are investigating the use of novel AAV capsids in AAV-based therapies for five undisclosed ophthalmic conditions each with estimated U.S. prevalence ranging from 5,000 to 15,000 patients. In 2021, we shared data from studies in non-human primates that will help to determine optimal routes of administration and we believe we have made significant progress toward measuring efficacy in the preclinical setting. We have also generated appropriate mouse models, produced research grade vectors, and started dosing mice in proof-of-concept studies that we hope will yield data beginning in the third quarter of 2022 to support pre-IND meetings with the FDA in the second half of 2022 or early 2023.

Preferred Stock Offering

On May 2, 2022, we consummated an offering with certain institutional investors for the private placement of 1,000,006 shares of our Series A Convertible Redeemable Preferred Stock (the "Series A Preferred Stock") and 250,005 shares of our Series B Convertible Redeemable Preferred Stock (the "Series B Preferred Stock, and together with the Series A Preferred Stock, together the "Preferred Stock"). The shares, which have since been redeemed in accordance with their terms described below, and are thus no longer outstanding as of June 30, 2022, had an aggregated stated value of $25.0 million. Each share of the Preferred Stock had a purchase price of $19.00, representing an original issue discount of 5% of the stated value. The Preferred Stock was convertible, at the option of the holders and, in certain circumstances, by us, into shares of Common Stock at a conversion price of $11.25 per share. The holders of the Series A Preferred Stock and Series B Preferred Stock had the right to require us to redeem their shares of preferred stock for cash at 105% of the stated value of such shares commencing after the earlier of the receipt of stockholder approval of an amendment to our Restated Certificate of Incorporation to effect a reverse stock split and 60 days after the closing of the issuances of the Series A Preferred Stock and Series B Preferred Stock and until 90 days after such closing. We had the option to redeem the Series A Preferred Stock for cash at 105% of the stated value commencing after the 90th day following the closing of the issuance of the Series A Preferred Stock, subject to the holders' rights to convert the shares prior to such redemption. On June 17, 2022, the holders of all 1,000,006 shares of Series A Preferred Stock and 250,005 shares of Series B Preferred Stock exercised their right to cause us to redeem all of such shares at a price equal to 105% of the stated value.

Reverse Stock Split

On June 30, 2022, we filed a Certificate of Amendment to our Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Certificate of Amendment"), to effectuate a reverse stock split of our outstanding common stock, par value $0.01 per share at an exchange ratio of 25-to-1 (the "Reverse Stock Split"). The Reverse Stock Split was effective on July 1, 2022. The number of authorized shares of our common stock immediately after the Reverse Stock Split remained at 200,000,000 shares.

Nasdaq Compliance

On July 19, 2022, we received formal notification from the Nasdaq Stock Market LLC confirming that we had regained compliance with Nasdaq Listing Rule 5550(a)(2), which requires that our common stock maintain a minimum bid price of at least $1.00 per share, and confirming that the matter is now closed.

RESULTS OF OPERATIONS

Comparison of Three Months Ended June 30, 2022 and June 30, 2021

	For the three months ended		Change	
($ in thousands)	**June 30, 2022**	**June 30, 2021**	**$**	**%**
Revenues:				
License and other revenues	$ 1,000	$ —	$ 1,000	N/A
Expenses:				
Royalties	350	—	350	N/A
Research and development	6,658	8,533	(1,875)	(22)%
General and administrative	3,460	5,182	(1,722)	(33)%
Impairment of construction-in-progress	(1,460)	—	(1,460)	N/A
Total expenses	9,008	13,715	(4,707)	(34)%
Loss from operations	(8,008)	(13,715)	5,707	(42)%
Interest and other income	30	8	22	275%
Interest expense	(317)	(1,500)	1,183	(79)%
Net loss	$ (8,295)	$ (15,207)	$ 6,912	(45)%

N/A - not applicable or not meaningful

License and other revenues

License and other revenues for the three months ended June 30, 2022 was $1.0 million, as compared to nil for the same period of 2021. The revenue in 2022 resulted from a clinical milestone achieved in the second quarter of 2022 under a sublicense agreement we entered into with Taysha Gene Therapies ("Taysha") in October 2020 relating to an investigational AAV-based gene therapy for Rett syndrome ("Rett"), including certain intellectual property relating to MECP2 gene constructs and regulation of their expression.

Royalties

Total royalties were $0.4 million for the three months ended June 30, 2022, as compared to nil for the same period of 2021, an increase of $0.4 million. The increase in expense was due to royalties owed to our licensors resulting from the $1.0 million milestone due from Taysha related to Rett.

Research and development

Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical and development costs, clinical trial costs, manufacturing and manufacturing facility costs, costs associated with regulatory approvals, depreciation on lab supplies and manufacturing facilities, and consultant-related expenses.

Total research and development spending for the three months ended June 30, 2022 was $6.7 million, as compared to $8.5 million for the same period of 2021, a decrease of $1.8 million. The decrease in expenses was primarily due to:

- decreased clinical and development work for our cell and gene therapy product candidates and other related costs of $0.5 million which is net of the $1.8 million pass through costs to Ultragenyx;
- decreased salary and related costs of $0.5 million; partially offset by
- decreased non-cash stock compensation expenses of $0.9 million.

We expect our research and development activities to continue as we attempt to advance our product candidates towards potential regulatory approval, reflecting costs associated with the following:

- employee and consultant-related expenses;
- preclinical and developmental costs;
- clinical trial costs;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with regulatory approvals.

General and administrative

General and administrative expenses primarily consist of payroll and personnel costs, office facility costs, public reporting company related costs, professional expenses (e.g., legal expenses) and other general operating expenses not otherwise included in research and development expenses. We expect to continue to incur our general and administrative costs as we seek potential regulatory approval and potential commercialization of our product candidates.

Total general and administrative expenses were $3.5 million for the three months ended June 30, 2022, as compared to $5.2 million for the same period of 2021, a decrease of $1.7 million. The decrease in expenses was primarily due to:

- decreased professional fees of $0.8 million;
- decreased non-cash stock-based compensation of $0.8 million; and
- decreased other costs of $0.1 million.

Impairment of construction-in-progress

Impairment for construction-in-progress was $(1.5) million for the three months ended June 30, 2022, as compared to nil in the same period of 2021. The construction-in-progress was for a facility for the ABO-102 and ABO-101 development programs. As a result of our shift in priorities, we determined the remaining value of the construction-in-progress facility had no future value and thus, we recorded impairment of $3.3 million for the three months ended March 31, 2022. We subsequently received certain refunds pertaining to the planned facility build-out, which reduced the overall impairment charge by $1.5 million for the three months ended June 30, 2022.

Interest and other income

Interest and other income was $30,000 for the three months ended June 30, 2022, as compared to $8,000 in the same period of 2021. The increase resulted from higher earnings on short-term investments driven by higher interest rates partially offset by a lower average balance of short-term investments.

Interest expense

Interest expense was $0.3 million for the three months ended June 30, 2022, as compared to $1.5 million in the same period of 2021. The decrease results primarily from the resolution of a disputed liability owed to our prior licensor, REGENXBIO, Inc.

Comparison of Six Months Ended June 30, 2022 and June 30, 2021

	For the six months ended		Change	
($ in thousands)	June 30, 2022	June 30, 2021	$	%
Revenues:				
License and other revenues	$ 1,346	$ —	$ 1,346	N/A
Expenses:				
Royalties	350	—	350	N/A
Research and development	17,203	16,868	335	2%
General and administrative	7,684	11,444	(3,760)	(33)%
Impairment of licensed technology	1,355	—	1,355	N/A
Impairment of right-of-use lease asset	1,561	—	1,561	N/A
Impairment of construction-in-progress	1,792	—	1,792	N/A
Total expenses	29,945	28,312	1,663	6%
Loss from operations	(28,599)	(28,312)	(287)	1%
Interest and other income	31	23	8	35%
Interest expense	(518)	(2,920)	2,402	(82)%
Net loss	$ (29,086)	$ (31,209)	$ 2,123	(7)%

N/A - not applicable or not meaningful

License and other revenues

License and other revenues for the six months ended June 30, 2022 was $1.3 million, as compared to nil for the same period of 2021. The revenue in 2022 resulted from a clinical milestone achieved in the second quarter of 2022 under a sublicense agreement we entered into with Taysha in October 2020 relating to an investigational AAV-based gene therapy for Rett syndrome, including certain intellectual property relating to MECP2 gene constructs and regulation of their expression. There was also revenue consisting of the recognition of deferred revenue related to grants for the ABO-102 and ABO-101 development programs.

Royalties

Total royalties were $0.4 million for the six months ended June 30, 2022, as compared to nil for the same period of 2021, an increase of $0.4 million. The increase in expense was due to royalties owed to our licensors resulting from the $1.0 million milestone due from Taysha related to Rett.

Research and development

Total research and development spending for the six months ended June 30, 2022 was $17.2 million, as compared to $16.9 million for the same period of 2021, an increase of $0.3 million. The increase in expenses was primarily due to:

- increased clinical and development work for our cell and gene therapy product candidates and other related costs of $1.8 million which is net of the $1.8 million pass through costs to Ultragenyx;
- increased other costs of $0.2 million; partially offset by
- decreased non-cash stock compensation expenses of $1.7 million.

General and administrative

Total general and administrative expenses were $7.7 million for the six months ended June 30, 2022, as compared to $11.4 million for the same period of 2021, a decrease of $3.7 million. The decrease in expenses was primarily due to:

- decreased professional fees of $2.9 million;
- decreased non-cash stock-based compensation of $1.1 million; partially offset by
- increased other costs of $0.3 million.

Impairment of licensed technology

Impairment of licensed technology was $1.4 million for the six months ended June 30, 2022, as compared to nil in the same period of 2021. The licensed technology was for the ABO-102 and ABO-101 development programs and as a result of our shift in priorities, we determined the remaining value of the licensed technology had no future value and thus, we recorded impairment of $1.4 million for the six months ended June 30, 2022.

Impairment of right-of-use lease asset

Impairment of right-of-use lease asset was $1.6 million for the six months ended June 30, 2022, as compared to nil in the same period of 2021. The impairment was related to a lease for a future manufacturing facility for the ABO-102 and ABO-101 development programs and as a result of our shift in priorities, we determined the remaining value of the portion of this lease had no future value and thus, we recorded impairment of $1.6 million for the six months ended June 30, 2022.

Impairment of construction-in-progress

Impairment of construction-in-progress was $1.8 million for the six months ended June 30, 2022, as compared to nil in the same period of 2021. The construction-in-progress was for a facility for the ABO-102 and ABO-101 development programs. As a result of our shift in priorities, we determined the remaining value of the construction-in-progress facility had no future value and thus, we recorded impairment of $1.8 million for the six months ended June 30, 2022.

Interest and other income

Interest and miscellaneous income was $31,000 for the six months ended June 30, 2022, as compared to $23,000 in the same period of 2021. The increase resulted from higher earnings on short-term investments driven by higher interest rates partially offset by a lower average balance of short-term investments.

Interest expense

Interest expense was $0.5 million for the six months ended June 30, 2022, as compared to $2.9 million in the same period of 2021. The decrease results primarily from the resolution of a disputed liability owed to our prior licensor, REGENXBIO, Inc.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows for the Six Months Ended June 30, 2022 and 2021

	For the six months ended June 30,	
($ in thousands)	**2022**	**2021**
Total cash and cash equivalents (used in) /provided by:		
Operating activities	$ (22,700)	$ (25,074)
Investing activities	(323)	31,300
Financing activities	(3,782)	8,357
Net (decrease) increase in cash and cash equivalents	$ (26,805)	$ 14,583

Operating activities

Net cash used in operating activities was $22.7 million for the six months ended June 30, 2022, primarily comprised of our net loss of $29.1 million and a decrease in operating assets and liabilities of $2.7 million, partially offset by net non-cash charges of $9.1 million.

Net cash used in operating activities was $25.1 million for the six months ended June 30, 2021, primarily comprised of our net loss of $31.2 million and a decrease in operating assets and liabilities of $0.7 million, partially offset by net non-cash charges of $6.8 million.

Investing activities

Net cash used in investing activities was $0.3 million for the six months ended June 30, 2022, primarily comprised of proceeds from maturities of short-term investments of $32.7 million and proceeds from disposal of property and equipment of $1.5 million, partially offset by purchases of short-term investments of $34.4 million and capital expenditures of $0.1 million.

Net cash provided by investing activities was $31.3 million for the six months ended June 30, 2021, primarily comprised of proceeds from maturities of short-term investments of $47.0 million, partially offset by purchases of short-term investments of $15.2 million and capital expenditures of $0.5 million.

Financing activities

Net cash used in financing activities was $3.8 million for the six months ended June 30, 2022, primarily comprised of the proceeds and redemption of our convertible redeemable preferred stock.

Net cash provided by financing activities was $8.4 million for the six months ended June 30, 2021, primarily comprised of proceeds of $7.7 million from open market sales of common stock pursuant to the ATM Agreement (as defined below) and proceeds of $0.7 million from the exercise of stock options.

We have historically funded our operations primarily through sales of common stock. The COVID-19 pandemic has negatively affected the global economy and created significant volatility and disruption of financial markets. An extended period of economic disruption could negatively affect our business, financial condition, and access to sources of liquidity.

Our principal source of liquidity is cash, cash equivalents, restricted cash and short-term investments, collectively referred to as our cash resources. As of June 30, 2022, our cash resources were $26.0 million. We believe that our current cash and cash equivalents, restricted cash and short-term investments are only sufficient to fund our operating expenses into the second quarter of 2023. However, in order to further advance development and seek potential regulatory approval of our investigational EB-101 product for RDEB, or to advance any of our preclinical AAV-based ophthalmology assets, we would need to secure additional funds through equity or debt offerings, potential upfront payments from potential commercial partners, potential sale of a priority review voucher, or other potential sources. We cannot be certain that additional funding will be available on acceptable terms, or at all. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern.

We have an open market sale agreement with Jefferies LLC (as amended, the "ATM Agreement") pursuant to which, we may sell from time to time, through Jefferies LLC, shares of our common stock for an aggregate sales price of up to $150.0 million. Any sales of shares pursuant to this agreement are made under our effective "shelf" registration statement on Form S-3 that is on file with and has been declared effective by the SEC. We did not sell any shares of our common stock under the ATM Agreement during the six months ended June 30, 2022. Cumulatively, as of June 30, 2022, we have sold an aggregate of 270,350 shares of our common stock under the ATM Agreement and received $25.0 million of net proceeds.

Since our inception, we have incurred negative cash flows from operations and have expended, and expect to continue to expend, substantial funds to complete our planned product development efforts. We have not been profitable since inception and to date have received limited revenues from the sale of products. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials, and regulatory compliance and cannot provide assurance that we will ever be able to generate sufficient product sales or royalty revenue to achieve profitability on a sustained basis, or at all.

If we raise additional funds by selling additional equity securities, the relative equity ownership of our existing investors will be diluted, and the new investors could obtain terms more favorable than previous investors. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

We are carefully and continually reassessing key business activities and all associated spending decisions. Nonetheless, we are spending necessary funds on manufacturing activities and preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds depend on many factors, including:

- the successful development and commercialization of our cell and gene therapy and other product candidates;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development, and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting, and enforcing patent claims;
- the costs involved in conducting clinical trials;
- any continuing impact to our business, operations, and clinical programs from the COVID-19 pandemic and government actions related thereto;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- the successful outcome of our regulatory filings.

Due to uncertainties and certain of the risks described above, our ability to successfully commercialize our product candidates, our ability to obtain applicable regulatory approval to market our product candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products, the potential necessity of licensing technology from third parties and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risks above.

We plan to continue our policy of investing any available funds in suitable certificates of deposit, money market funds, government securities and investment-grade, interest-bearing securities. We do not invest in derivative financial instruments.

Critical Accounting Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- it requires assumptions to be made that were uncertain at the time the estimate was made, and
- changes in the estimate or different estimates that could have been selected could have material impact in our results of operations or financial condition.

While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results could differ from those estimates and the differences could be material. For a discussion of the critical accounting estimates that affect the unaudited condensed consolidated financial statements, see "Critical Accounting Estimates" included in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report.

See Note 1 to our unaudited condensed consolidated financial statements for a discussion of our significant accounting policies.

Recently Issued Accounting Standards Not Yet Effective or Adopted

Management does not believe that any recently issued, but not yet effective accounting pronouncements, if adopted, would have a material impact on the accompanying condensed consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management and consultants, including the Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), we have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls and Procedures"), as of June 30, 2022, as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Conclusion of Evaluation — Based on this Disclosure Controls and Procedures evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our Disclosure Controls and Procedures as of June 30, 2022 were effective.

Changes in Internal Control Over Financial Reporting – There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None

ITEM 1A. RISK FACTORS

Our business and financial results are subject to numerous risks and uncertainties. As a result, the risks and uncertainties discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2021 should be carefully considered. Aside from the risk factor below, there have been no material changes in the assessment of other risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2021.

There is substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing. If we do not continue as a going concern, investors could lose their entire investment.

Our financial statements as of June 30, 2022 have been prepared under the assumption that we will continue as a going concern for the next 12 months. As of June 30, 2022, our current cash and cash equivalents, restricted cash and short-term investments were $26.0 million. We believe that our current cash resources are only sufficient to fund our operating expenses into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our ability to continue as a going concern will depend on our ability to obtain additional funding, as to which no assurances can be given. To further advance development and seek potential regulatory approval of our lead product for RDEB or to advance any of our preclinical ophthalmology assets, we would need to secure additional funds through equity or debt offerings, potential upfront payments from potential commercial partners, potential sale of a priority review voucher, or other potential sources. Our future success depends on our ability to raise capital or implement the various strategic alternatives discussed above. We cannot be certain that these initiatives or raising additional capital will be available to us or, if available, will be on terms acceptable to us. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs, forego future development and other opportunities, or even terminate our operations.

ITEM 6. EXHIBITS

See Exhibit Index below, which is incorporated by reference herein.

Exhibit Index

Exhibits:

3.1	Certificate of Amendment to Restated Certificate of Incorporation of Abeona Therapeutics Inc. (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on June 30, 2022).
3.2	Amendment No. 1 to the Amended and Restated Bylaws of Abeona Therapeutics Inc. (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on April 29, 2022).
3.3	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on May 2, 2022).
3.4	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Redeemable Preferred Stock (incorporated by reference to Exhibit 3.2 of our Form 8-K filed on May 2, 2022).
10.1	Form of Securities Purchase Agreement between Abeona Therapeutics Inc. and the investors thereto, dated April 29, 2022 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on May 2, 2022).
10.2	Form of Registration Rights Agreement by and among Abeona Therapeutics Inc. and the investors named therein, dated April 29, 2022 (incorporated by reference to Exhibit 10.2 of our Form 8-K filed on May 2, 2022).
10.3†	License Agreement by and between Abeona Therapeutics Inc. and Ultragenyx Pharmaceutical Inc., dated May 16, 2022.
31.1	Principal Executive Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Principal Financial Officer Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32*	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Abeona's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, formatted in Inline XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets at June 30, 2022 and December 31, 2021, (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and six months ended June 30, 2022 and 2021, (iii) Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2022 and 2021, (iv) Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021, and (v) Notes to Condensed Consolidated Financial Statements.

* Pursuant to Item 601(b)(32)(ii) of Regulation S-K, this exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filing.

† Certain provisions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

SIGNATURES

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

ABEONA THERAPEUTICS INC.

Date:August 11, 2022

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date:August 11, 2022

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 10.3

SPECIFIC TERMS IN THIS AGREEMENT HAVE BEEN REDACTED BECAUSE SUCH TERMS ARE BOTH NOT MATERIAL AND ARE OF A TYPE THAT ABEONA THERAPEUTICS INC. TREATS AS CONFIDENTIAL. THESE REDACTED TERMS HAVE BEEN MARKED IN THIS EXHIBIT AT THE APPROPRIATE PLACE WITH THREE ASTERISKS [***]

LICENSE AGREEMENT

BETWEEN

ULTRAGENYX PHARMACEUTICAL INC.

AND

ABEONA THERAPEUTICS INC.

May 16, 2022

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THIS LICENSE AGREEMENT (this "**Agreement**") is entered into as of May 16, 2022 (the "**Effective Date**") by and between Abeona Therapeutics Inc., a Delaware corporation having its principal place of business at 1330 Avenue of the Americas, 33rd Fl, New York, New York 10019, United States ("**Abeona**"), and Ultragenyx Pharmaceutical Inc., a Delaware corporation having offices at 60 Leveroni Court, Novato, California 94949, United States ("**Ultragenyx**").

INTRODUCTION

WHEREAS, Abeona Controls certain Patents, Know-How and other intellectual property rights related to ABO-102, a proprietary AAV gene therapy for the treatment of MPS IIIA;

WHEREAS, Abeona and Ultragenyx are parties to that certain Assignment Agreement, dated as of the date hereof, pursuant to which Abeona agreed to assign to Ultragenyx the Nationwide Children's Agreement and certain rights and obligations of Abeona thereunder related to the development and manufacture of ABO-102 (the "**Assignment Agreement**"); and

WHEREAS, Ultragenyx wishes to obtain from Abeona and Abeona wishes to grant to Ultragenyx certain rights and licenses under certain Patents, Know-How, and other intellectual property rights Controlled by Abeona to Develop, Manufacture, and Commercialize ABO-102 and associated Licensed Products in the Territory, subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

The following terms used in this Agreement will have the meanings set forth in this ARTICLE 1:

1.1 "**AAA**" has the meaning set forth in Section 13.4.

1.2 "**AAV**" means adeno-associated virus.

1.3 "**Abeona**" has the meaning set forth in the preamble.

1.4 "**Abeona Indemnified Party**" has the meaning set forth in Section 10.1.

1.5 "**Abeona Sole Inventions**" has the meaning set forth in Section 7.1.2.

1.6 "**ABO-102**" means the product identified in Investigational New Drug Application (IND) 016850, Serial Submission 0034 - Date of Submission: 13 February 2020 pages 4-6.

1.7 "**Accounting Standards**" means, with respect to a Party or its Affiliate or Sublicensee, in conformance with U.S. GAAP, as such Party, Affiliate or Sublicensee uses for its financial reporting obligations, consistently applied.

1.8 "**Action**" means any claim, action, cause of action or suit (whether in contract or tort or otherwise), litigation (whether at law or in equity, whether civil or criminal), assessment, arbitration, investigation, hearing, charge, complaint, demand, notice or proceeding of, to, from, by or before any Governmental Authority.

1.9 "**Affiliate**" means, as of any point in time and for so long as such relationship continues to exist with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person. A Person will be regarded as in control of another Person if, at the time of such determination, it (a) owns or controls, directly or indirectly, more than fifty percent (50%) of the equity securities of the subject Person entitled to vote in the election of directors (or, in the case of a Person that is not a corporation, for the election of the corresponding managing authority), or (b) possesses, directly or indirectly, the power to direct or cause the direction of the management or policies of such Person (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.10 "**Agreement**" has the meaning set forth in the preamble.

1.11 "**Applicable Law**" means any applicable federal, state, local, municipal, foreign, or other law, statute, legislation, constitution, principle of common law, code, treaty, ordinance, regulation, rule, or order of any kind whatsoever put into place under the authority of any Governmental Authority, including the FFDCA, PHSA, Prescription Drug Marketing Act, the Generic Drug Enforcement Act of 1992 (21 U.S.C. §335a et seq.), U.S. Patent Act (35 U.S.C. §1 et seq.), Federal Civil False Claims Act (31 U.S.C. §3729 et seq.), and the Anti-Kickback Statute (42 U.S.C. §1320a-7b et seq.), all as amended from time to time, together with any rules, regulations, and compliance guidance promulgated thereunder. For the avoidance of doubt, "Applicable Law" will include the applicable regulations and guidance of the FDA and EMA (and national implementations thereof) that constitute GLP, GMP, and GCP (and, if and as appropriate under the circumstances, ICH guidance or other comparable regulation and guidance of any applicable Governmental Authority).

1.12 "**Assignment Agreement**" has the meaning set forth in the recitals hereto.

1.13 "**Auditor**" has the meaning set forth in Section 6.9.1.

1.14 "**Bankrupt Party**" has the meaning set forth in Section 2.6.

1.15 "**Bankruptcy Code**" has the meaning set forth in Section 2.6.

1.16 "**Biosimilar Application**" has the meaning set forth in Section 7.2.4(c).

1.17 "**Biosimilar Product**" means any biological product sold by a Third Party not authorized by Ultragenyx or its Affiliates or its or their Sublicensees that obtained Regulatory Approval for use in such country through an application or submission filed with the applicable Regulatory Authority pursuant to a process governing approval of biologics biosimilar to or interchangeable with a Licensed Product or otherwise relying on the approval of such Licensed Product in such country, including an application filed under 42 U.S.C. § 262(k) in the United States or any similar provisions in a country outside the United States that rely, at least in part, on the Regulatory Approval of, or the data submitted in connection with a Regulatory Approval of, such Licensed Product.

1.18 "**BLA**" means a Biologics License Application filed with the FDA in the United States, as defined in Title 21 of the U.S. Code of Federal Regulations, Section 601.2, or any non-U.S. counterpart of the foregoing.

1.19 "**Blocking IP**" has the meaning set forth in Section 6.4.1.

1.20 “**Breaching Party**” has the meaning set forth in Section 12.3.1.

1.21 “**Business Day**” means a day, other than a Saturday, Sunday or holiday on which banks located in New York are authorized to be closed (as such holidays are listed on the New York State, Department of Financial Services website (by way of example, www.dfs.ny.gov/industry_guidance/bank_holidays_2022 for Calendar Year 2022)).

1.22 “**Calendar Quarter**” means each of the three month periods ending on March 31, June 30, September 30, and December 31 of any Calendar Year; provided, however: (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the Calendar Quarter in which the Effective Date occurs; and (b) the last Calendar Quarter will extend from the beginning of the Calendar Quarter in which this Agreement expires or terminates until the effective date of such expiration or termination.

1.23 “**Calendar Year**” means, for the first Calendar Year, the period beginning on the Effective Date and ending on December 31, 2022, and for each Calendar Year thereafter each twelve (12)-month period commencing on January 1, and ending on December 31, except that the last Calendar Year will commence on January 1 of the year in which this Agreement expires or terminates and end on the effective date of such expiration or termination.

1.24 “**Change of Control**” means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s business to which the subject matter of this Agreement relates.

1.25 “**Clinical Data**” means the original human subject data and case report forms (CRFs) collected or generated with respect to Clinical Studies of any Licensed Product, together with all analysis, reports, and results with respect thereto.

1.26 “**Clinical Study**” means a study in which human subjects or patients are dosed with a product, whether approved or investigational, pursuant to a prospectively defined clinical trial protocol.

1.27 “**CMO**” means any Third Party contract manufacturing organization.

1.28 “**Combination Product**” has the meaning set forth in Section 1.82.

1.29 “**Commercialize**” means, in respect of a Licensed Product, to (a) market, advertise, promote, detail, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise exploit, (b) conduct activities, other than Development and Manufacturing, in preparation for the foregoing activities, including obtaining Pricing and Reimbursement Approval, (c) conduct post-Regulatory Approval commitments or studies, or (d) conduct other activities in connection with the foregoing activities, including activities related to medical affairs matters, sales force matters, and pharmacovigilance matters. Cognates of the word “Commercialize” will have correlative meanings.

1.30 "**Commercially Reasonable Efforts**" means, with respect to each Party, such efforts that are consistent with the efforts and resources normally used by a biopharmaceutical company that is of comparable size and scope to such Party in the exercise of its reasonable business discretion relating to a research and development program or pharmaceutical product owned by it or to which it has exclusive rights, with similar characteristics as a Licensed Product, which is of similar market potential at a similar stage in its development or product life as a Licensed Product, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position, the regulatory structure involved, profitability (including pricing and reimbursement status achieved or projected to be achieved), and other relevant factors, including technical, legal, scientific or medical factors. For purposes of clarity, it is anticipated that the level of effort may be different for different markets and may change over time, reflecting changes in the status of the product and the market(s) involved.

1.31 "**Confidential Information**" means (a) all trade secrets or confidential or proprietary information (including any tangible materials embodying any of the foregoing) of the disclosing Party or its Affiliates provided or disclosed to the other Party or any of its Affiliates in connection with this Agreement, (b) "Confidential Information" (as defined in the Prior CDA) that was disclosed by a Party or any of its Affiliates to the other Party or any of its Affiliates under the Prior CDA, and (c) the terms and conditions of this Agreement; provided, however, that Confidential Information will not include information that:

(i) becomes part of the public domain through no breach of this Agreement on the part of the receiving Party;

(ii) was in the receiving Party's possession prior to disclosure by the disclosing Party hereunder, and not through a prior disclosure by the disclosing Party, without any obligation of confidentiality with respect to such information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);

(iii) is subsequently received by the receiving Party from a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party under any agreement between such Third Party and the disclosing Party; or

(iv) has been independently developed by or for the receiving Party without reference to, or use or disclosure of, the disclosing Party's Confidential Information (as evidenced by the receiving Party's or such Affiliate's written records or other competent evidence);

provided, further, that clauses (ii) through (iv) above will not apply to the terms and conditions of this Agreement.

1.32 "**Control**" or "**Controlled**" means, with respect to any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right, the legal authority or right (whether by ownership, license (other than a license granted pursuant to this Agreement) or otherwise) of a Person or its Affiliate, to grant access, a license or a sublicense of or under such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right without (a) breaching the terms of any agreement with a Third Party and (b) paying any consideration to any Third Party, except for that which a Party in-licenses and is included within the Licensed Technology as contemplated in Section 6.4.1. Notwithstanding anything in this Agreement to the contrary, a Party will be deemed not to Control any Know-How, Patent, Regulatory Material, Regulatory Approval or other property right that is owned or in-licensed by an acquirer of such Party, except (i) with respect to any such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right arising from participation by employees or consultants of such acquirer in furtherance of this Agreement after the relevant Change of Control, (ii) to the extent that any such Know-How, Patent, Regulatory Material, Regulatory Approval or other property right is included in or used in furtherance of the this Agreement by the acquirer after such Change of Control, or (iii) for intellectual property rights constituting improvements (or direct improvements to such improvements) to the Know-How or Patents Controlled by the other Party that are specific to a product in the Field, in each case, conceived, discovered, developed or otherwise made by any employees or consultants of the acquirer after such Change of Control but during the Transition Period.

1.33 "**Cover,**" "**Covering**" or "**Covered**" means, when referring to a Licensed Product: (a) with respect to a Patent, that, in the absence of a license granted to a Person under an issued claim included in such Patent, the practice by such Person of a specified activity with respect to such Licensed Product would infringe such claim, or (b) with respect to an application for Patents, that, in the absence of a license granted to a Person under a claim included in such application, the practice by such Person of a specified activity with respect to such Licensed Product would infringe such claim if such patent application were to issue as a patent.

1.34 "**Development**" means, with respect to a Licensed Product, all (a) non-clinical and pre-clinical discovery, research and development activities and optimization completed prior to filing an IND with respect to such Licensed Product, including animal and toxicology studies, and (b) clinical and non-clinical research and development activities conducted after filing of an IND with respect to such Licensed Product, including toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Studies, regulatory affairs, pharmacovigilance, Clinical Study regulatory activities and obtaining and maintaining Regulatory Approval. Cognates of the word "Development" will have correlative meanings.

1.35 "**Disputes**" has the meaning set forth in Section 13.1.

1.36 "**Distributor**" means any Third Party appointed by Ultragenyx or any of its Affiliates or its or their Sublicensees to Commercialize Licensed Product in one or more countries in the Territory, in circumstances where such Third Party purchases its requirements of Licensed Product from Ultragenyx or its Affiliates or its or their Sublicensees and such Third Party does not pay Ultragenyx or any of its Affiliates or its or their Sublicensees consideration based on such Third Party's resales.

1.37 "**Dollars**" or "**US$**" means United States dollars.

1.38 "**Effective Date**" has the meaning set forth in the preamble.

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

1.40 "**Executive Officers**" has the meaning set forth in Section 13.3.

1.41 "**Existing Vendor**" means any Third Party that is a counterparty to an Existing Vendor Agreement.

1.42 "**Existing Vendor Agreements**" means the agreements set forth on Schedule 1.42.

1.43 "**Expedited Arbitration**" has the meaning set forth in Section 13.4.

1.44 "**Expedited Dispute**" has the meaning set forth in Section 13.4.

1.45 "**Exploit**" means to make, have made, use, distribute, offer for sale, sell, import or export, including to research, develop, modify, enhance, improve, register, distribute, commercialize, or otherwise dispose of. Cognates of the word "Exploit" will have correlative meanings.

1.46 "**External Costs**" means, with respect to a Party, costs and expenses paid by such Party or its Affiliates to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards), other than employees of such Party or its Affiliates. For clarity, with respect to Transition Costs, External Costs will include lease payments for shared work space in Spain, travel, general laboratory or office supplies, and all other general and administrative Third Party costs and expenses and overhead items, in each case, to the extent invoiced by a Third Party to a Party.

1.47 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.48 "**FFDCA**" means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), as amended from time to time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.49 "**Field**" means the treatment, palliation, diagnosis, cure or prevention of MPS IIIA in humans.

1.50 "**First Commercial Sale**" means, on a Licensed Product-by-Licensed Product basis, the first sale of such Licensed Product by a Selling Party to a Third Party resulting in Net Sales; provided that any sale of a Licensed Product to an Affiliate or Sublicensee will not constitute a First Commercial Sale. First Commercial Sale includes the first such sale to a Third Party for patient assistance, named patient use, or other similar programs or studies for which a Selling Party receives Net Sales.

1.51 "**FTE**" means the equivalent of a full-time individual's work, performed by one or more employees, at [***] hours per year for a twelve-month period, carried out by an appropriately qualified employee of a Party or its Affiliates performing activities pursuant to this Agreement. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (e.g., time- and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. For clarity, Third Party contractors or indirect personnel (including support functions such as managerial, financial, legal or business development) will not constitute FTEs.

1.52 "**FTE Costs**" means, for any period, the FTE Rate multiplied by the number of FTEs who perform a specified activity under this Agreement. FTEs will be pro-rated as necessary.

1.53 "**FTE Rate**" means, (a) for individuals in the US, the rate of [***] Dollars ($[***]) per one full FTE per calendar month, and (b) for individuals outside the US, the rate of [***] Dollars ($[***]) per one full FTE per calendar month. The FTE Rate will be prorated on a daily basis as necessary. For clarity, such FTE Rate includes the cost of salaries, benefits, and insurance. Infrastructure costs, travel, general laboratory or office supplies, training, and all other general and administrative expenses and overhead items are not included within the FTE Rate.

1.54 "**GCP**" or "**Good Clinical Practice**" means all applicable then-current standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, (a) as set forth in the ICH Guideline for Good Clinical Practice and any other ICH guidelines for good clinical practice for Clinical Studies on medicinal products, (b) the Declaration of Helsinki (2013) as last amended at the 64th World Medical Association in October 2013 and any further amendments or clarifications thereto, (c) as set forth in the FFDCA and as promulgated in FDA regulations, including 21 C.F.R. Parts 11 (Electronic Records and Signatures), 50 (Protection of Human Subjects), 54 (Financial Disclosure by Clinical Investigators), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), and (d) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that Clinical Data and reported results are credible and accurate and the manner in which Clinical Studies are conducted protects the rights, integrity, and confidentiality of Clinical Study subjects.

1.55 "**GLP**" or "**Good Laboratory Practice**" means all applicable then-current standards for good laboratory practices, as set forth in the FDA's Good Laboratory Practice regulations in 21 C.F.R. Part 58, and such standards of good laboratory practice as are required by the equivalent Applicable Law in the relevant country and other organizations and Governmental Authorities in countries in which a Licensed Product is intended to be sold by the Party that is subject to such standards.

1.56 "**GMP**" or "**Good Manufacturing Practice**" means all applicable then-current standards for good manufacturing practices, including, as applicable, (a) the principles set forth in the FDA's Current Good Manufacturing Practices regulations in 21 C.F.R. §§ 210, 211, 600 and 610 and all other applicable FDA guidelines and requirements, (b) European Directive 2003/94/EC principles and guidelines of good manufacturing practice for medicinal products and investigational medicines for human use and all other applicable guidelines stated in the EudraLex guidelines relating to manufacturing of medicinal products, (c) manufacturing principles detailed in applicable ICH guidelines, and (d) all equivalent Applicable Law applicable to Manufacturing in any relevant country, each as may be amended and applicable from time to time.

1.57 "**Government Official**" (where "government" means all levels and subdivisions of governments, i.e., local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organization such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under local Applicable Law and not already covered by any of the above; and (e) any person acting in an official capacity for or on behalf of any of the above. "**Government Official**" will include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting a Party's business.

1.58 "**Governmental Authority**" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority or functions of any nature pertaining to government.

1.59 "**ICH**" means the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

1.60 "**IND**" means an Investigational New Drug application, clinical trial application or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformance with the requirement of such Regulatory Authority, and any amendments or supplements thereto.

1.61 "**Indemnified Party**" has the meaning set forth in Section 10.3.

1.62 "**Indemnifying Party**" has the meaning set forth in Section 10.3.

1.63 "**Infringement**" has the meaning set forth in Section 7.3.1.

1.64 "**Infringement Action**" has the meaning set forth in Section 7.3.2.

1.65 "**Infringement Claim**" has the meaning set forth in Section 7.4.

1.66 "**Inventory**" means all quantities of finished Licensed Product, or work in progress, in the possession or Control of Abeona or any of its Affiliates as of the Effective Date.

1.67 "**Joint Inventions**" has the meaning set forth in Section 7.1.3.

1.68 "**Joint Patents**" means the Patents Covering the Joint Inventions.

1.69 "**Joint Transition Team**" or "**JTT**" has the meaning set forth in Section 5.1.1.

1.70 "**Know-How**" means all Materials, inventions, practices, methods, protocols, formulae, knowledge, improvements, know-how, trade secrets, quality assurance, quality control, analytical test methods, processes, procedures, assays, skills, experience, techniques, technology, information, data and results of experimentation and testing, including pharmacological, toxicological and pre-clinical and clinical test data and analytical and quality control data, patentable or otherwise.

1.71 "**Licensed Know-How**" means any and all Know-How relating to any Licensed Product that is (a) Controlled by Abeona or its Affiliates as of the Effective Date, in each case, that is necessary or useful to Exploit any Licensed Product in the Field and in the Territory or (b) an Abeona Sole Invention that is described in clause (ii) of the definition thereof.

1.72 "**Licensed Patents**" means (a) the patent applications listed in Schedule 1.72 attached hereto, plus (i) all divisionals, continuations, continuations-in-part thereof or any other patent rights claiming priority directly or indirectly to any of the issued patents or patent applications identified on Schedule 1.72, and (ii) all patents issuing on any of the foregoing, together with all registrations, reissues, re-examinations, renewals, supplemental protection certificates and extensions of any of the foregoing, and all foreign counterparts thereof, (b) any other Patents, existing as of the Effective Date, Controlled by Abeona or its Affiliates or that are Joint Patents, in each case, that (i) claim the composition of matter, manufacture or use of any Licensed Product (including use as a monotherapy or in combination with other compositions of matter), or (ii) are necessary or useful for the research, Development, Manufacture, import, export, use, sale or Commercialization of any Licensed Products in the Field in the Territory, and (c) any Patents that claim Licensed Know-How existing as of the Effective Date that are filed with a patent office or relevant Governmental Authority after the Effective Date.

1.73 "**Licensed Product**" means any pharmaceutical product in final form containing: (a) ABO-102 or (b) any modification, enhancement or derivative of ABO-102, in each case ((a) and (b)), whether alone as the sole active component or as a combination with other active components, in any presentation, formulation or dosage form. For clarification, Licensed Product will include any Combination Product (provided, that no licenses granted by Abeona under Section 2.1 shall apply to any active components in a Combination Product other than ABO-102 or any modification, enhancement or derivative of ABO-102).

1.74 "**Licensed Technology**" means collectively, Licensed Patents, Licensed Know-How and Abeona's interest in Joint Inventions and Joint Patents.

1.75 "**Losses**" means damages, losses, liabilities, costs (including costs of investigation and defense), fines, penalties, taxes, expenses, or amounts paid in settlement (in each case, including reasonable attorneys' and experts' fees and expenses), in each case resulting from an Action.

1.76 "**Manufacture**" or "**Manufacturing**" means activities directed to making, having made, producing, manufacturing, analytical development, processing, formulating, filling, finishing, packaging, labeling, quality control testing and quality assurance release, shipping or storage of a Licensed Product by or on behalf of a Selling Party. References to a Person engaging in Manufacturing activities will include having any or all of the foregoing activities performed by a Third Party.

1.77 "**Materials**" means all tangible compositions of matter, devices, articles of manufacture, assays, biological, chemical, or physical materials, and other similar materials.

1.78 "**Milestone Event**" has the meaning set forth in Section 6.1.

1.79 "**Milestone Payment**" has the meaning set forth in Section 6.1.

1.80 "**MPS IIIA**" means Mucopolysaccharidosis type III A, which is also referred to as "Sanfilippo syndrome type A".

1.81 "**Nationwide Children's Agreement**" means the Exclusive License Agreement, by and between Nationwide Children's Hospital ("**Nationwide Children's**") and Abeona, effective as of November 8, 2013, as amended or restated from time to time.

1.82 "**Net Sales**" means, with respect to the Licensed Products, the gross amount received for all sales of such Licensed Products by Ultragenyx and its Affiliates and Sublicensees (each, a "**Selling Party**") to a Third Party (other than another Selling Party, unless such Selling Party is the end user of such Licensed Product), less the following deductions actually incurred or paid or otherwise accrued, allowed, reserved or allocated in accordance with Ultragenyx's Accounting Standards:

(a) normal and customary trade, cash and quantity discounts, allowances and credits for such Licensed Products;

(b) fees paid, reserves, and allowances to distributors and discounts (including cash, quantity and patient program discounts), charge-back payments, rebates and similar payments granted to customers, wholesalers, distributors, buying groups, retailers, health care insurance carriers, pharmacy benefit management companies, health maintenance organizations, managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers;

(c) clawbacks of any payments made to a Selling Party;

(d) credits or allowances actually granted for price adjustments (including retroactive price adjustments), damaged goods, spoiled product, claims, recalls, rejections or returns of such Licensed Products, including such Licensed Products returned in connection with withdrawals;

(e) freight out, postage, customs charges, shipping and insurance charges for delivery of such Licensed Products; and

(f) taxes or duties levied on, absorbed by, or otherwise imposed on the sale of such Licensed Products, including value-added taxes, or other governmental charges otherwise imposed upon the billed amount, as adjusted for rebates and refunds, to the extent not paid by the Third Party, but excluding any income taxes.

The following will not give rise to Net Sales: any dispositions of any Licensed Products for pre-clinical or clinical testing required in connection with obtaining Regulatory Approval or Pricing and Reimbursement Approval of any Licensed Products nor any dispositions or use of any Licensed Products under compassionate use, patient assistance, named patient use, or other similar programs or studies where the Licensed Product is supplied without charge or below manufacturing cost.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product will be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average net selling price in such country of the relevant Licensed Product if sold separately in such country and B is the average net selling price in such country of, as applicable, each product that contains the Other Items contained in such Combination Product if sold separately in such country. If either such Licensed Product or the relevant Other Item(s) is not sold separately (including in the case of the sale of a combination therapy that contains the Licensed Product but is not sold separately) in a particular country, then the adjustment to Net Sales will be determined by the Parties in good faith to reasonably reflect the fair market value of the contribution of such Licensed Product or product in such Combination Product to the total fair market value of such Combination Product.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts and other forms of reimbursements will be allocated among products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Ultragenyx's, its Affiliates' or its or their Sublicensees' existing allocation method; provided that any such allocation will be done in accordance with Applicable Law, including any price reporting laws, rules and regulations and such allocation method will not disproportionately reduce Net Sales in favor of net sales of other products.

For the purposes of calculating Net Sales, all Net Sales will be converted into Dollars pursuant to Section 6.12.

Subject to the above, all sales and deductions included within Net Sales will be calculated in accordance with the standard internal policies and procedures of Ultragenyx, its Affiliates or its or their Sublicensees, which will be in accordance with applicable Accounting Standards. Notwithstanding anything herein to the contrary, in the event that a Selling Party will receive payment for a Licensed Product on an installment basis, the Parties will apply the pro-rata amount of the installment received to Net Sales with respect to such Licensed Product.

As used herein, "**Combination Product**" means any Licensed Product in combination with one or more Other Items either when (A) priced and sold in a single package containing such multiple products or (B) packaged separately but sold together for a single price or where a discount, rebate or other amount is provided in exchange for (or otherwise conditioned upon) the purchase of such Other Item, in each case ((A) and (B)), including all dosage forms, formulations, presentations, and package configurations. "**Other Item**" means any therapeutically active pharmaceutical ingredient other than the therapeutically active pharmaceutical ingredient(s) of the Licensed Product.

1.83 "**Other Item**" has the meaning set forth in Section 1.82.

1.84 "**Non-Breaching Party**" has the meaning set forth in Section 12.3.1.

1.85 "**Party**" means either Abeona or Ultragenyx; "**Parties**" means Abeona and Ultragenyx, collectively.

1.86 "**Patents**" means the rights and interests in and to (a) all patents and patent applications (including provisional applications), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, re-issues, additions, renewals, extensions, confirmations, registrations, any other pre- or post-grant forms of any of the foregoing, (b) any confirmation patent or registration patent or patent of addition, utility models, patent term extensions, and supplemental protection certificates or requests for continued examinations, foreign counterparts, and the like of any of the foregoing, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, including author certificates, utility models, petty patents, innovation patents and design patents and certificates of invention.

1.87 "**Person**" means any natural person, corporation, general partnership, limited partnership, joint venture, proprietorship or other business organization or a Governmental Authority.

1.88 "**Pricing and Reimbursement Approval**" means, with respect to a Licensed Product, the governmental approval, agreement, determination or decision establishing the price or level of reimbursement for such Licensed Product, in a given country in the Territory prior to the sale of such Licensed Product in such jurisdiction in the Territory.

1.89 "**Prior CDA**" means the Mutual Confidential Disclosure Agreement by and between the Parties, dated January 13, 2021, as amended by the First Amendment, dated February 2, 2022.

1.90 "**Prior Development Costs**" has the meaning set forth on Schedule 4.1.3.

1.91 "**Prosecute**" or "**Prosecution**" means in relation to any Patents, (a) to prepare and file patent applications, including re-examinations or re-issues thereof, and represent applicants or assignees before relevant patent offices or other relevant Governmental Authorities during examination, re-examination and re-issue thereof, in appeal processes, interferences, oppositions or any equivalent proceedings, (b) to defend all such applications against Third Party oppositions or other challenges, (c) to secure the grant of any patents arising from such patent application, (d) to maintain in force any issued patent (including through payment of any relevant maintenance fees), and (e) to make all decisions with regard to any of the foregoing activities.

1.92 "**Public Health Service Act**" or "**PHSA**" means the United States Public Health Service Act (42 U.S.C. 201 et seq.), as amended.

1.93 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval, license, registration or authorization by the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in the Field in such country, excluding, in each case, separate Pricing and Reimbursement Approval that may be required.

1.94 "**Regulatory Authority**" means, with respect to a particular country, any multinational, federal, national, state, provincial or local regulatory agency, department, bureau or other Governmental Authority with authority over the Development, Manufacture, or Commercialization or granting of Regulatory Approval of a Licensed Product in such country, including, but not limited to, the FDA and EMA.

1.95 "**Regulatory Exclusivity**" means, with respect to each Licensed Product in any country in the Territory, any data exclusivity rights, market exclusivity rights, or other exclusive right (other than Patents exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such country that prevents the approval or marketing of any Biosimilar Product of such Licensed Product in such country, including reference product exclusivity under Section 351(k)(7)(C) of the PHSA and pediatric exclusivity under Section 351(m) of the same and any foreign equivalents.

1.96 "**Regulatory Materials**" means (a) any regulatory application, submission, notification, communication, correspondence, registration, Regulatory Approvals and other filings made to, received from or otherwise conducted with a Regulatory Authority related to Developing, Manufacturing, obtaining Regulatory Approval, marketing, selling or otherwise Commercializing a pharmaceutical product in a particular country or jurisdiction, (b) all supplements and amendments to any of the foregoing, and (c) all data, including Clinical Data, and other information contained in any of the foregoing.

1.97 "**ROFR Negotiation Period**" has the meaning set forth in Section 2.6.

1.98 "**ROFR Notice**" has the meaning set forth in Section 2.6.

1.99 "**ROFR Transaction**" has the meaning set forth in Section 2.6.

1.100 "**Royalty Term**" means, on a Licensed Product-by-Licensed Product basis, the period commencing on the date of the First Commercial Sale of such Licensed Product and ending upon the last of the following to occur: (a) the expiration of the last-to-expire Valid Claim that Covers such Licensed Product in any country; and (b) the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product.

1.101 "**Selling Party**" has the meaning set forth in Section 1.82.

1.102 "**Sole Inventions**" has the meaning set forth in Section 7.1.2.

1.103 "**Sublicense**" means a grant of rights from Ultragenyx to a Sublicensee under any of the rights licensed to Ultragenyx by Abeona under Section 2.1.

1.104 "**Sublicensee**" means a Person, other than an Affiliate or a Distributor of Ultragenyx, that is granted a sublicense by Ultragenyx or its Affiliates to the rights granted to Ultragenyx in Section 2.1, as provided in Section 2.3.

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

1.106 "**Territory**" means worldwide.

1.107 "**Third Party**" means any Person other than a Party or any of its Affiliates.

1.108 "**Third Party License**" has the meaning set forth in Section 6.4.1.

1.109 "**Third Party Losses**" means Losses resulting from an Action by a Third Party.

1.110 "**Transition Costs**" means with respect to a Calendar Quarter, the FTE Costs plus the External Costs actually incurred in connection with the Transition Services for such Calendar Quarter as set forth in the Transition Plan.

1.111 "**Transition Period**" means the period commencing on the Effective Date and ending upon the earlier of (a) the completion of all activities set forth in the agreed-upon Transition Plan and (b) December 31, 2022. The Transition Period may be extended by mutual written agreement of both Parties set forth in Section 3.1.1.

1.112 "**Transition Plan**" has the meaning set forth in Section 3.1.2.

1.113 "**Transition Services**" has the meaning set forth in Section 3.1.2.

1.114 "**Ultragenyx**" has the meaning set forth in the preamble.

1.115 "**Ultragenyx Indemnified Party**" has the meaning set forth in Section 10.1.

1.116 "**Ultragenyx Patents**" has the meaning set forth in Section 7.1.2.

1.117 "**Ultragenyx Sole Inventions**" has the meaning set forth in Section 7.1.2.

1.118 "**United States**" or "**U.S.**" or "**US**" means the United States and its territories, possessions and commonwealths.

1.119 "**Upstream Patent**" means any Patent exclusively licensed to Abeona under the Nationwide Children's Agreement (prior to the assignment of thereof).

1.120 "**Valid Claim**" means a claim of any issued, unexpired patent within the Upstream Patents, the Licensed Patents or the Joint Patents that has not been irrevocably or unappealably disclaimed or abandoned, or been held unenforceable, unpatentable or invalid by a final, non-appealable decision of a court or other Governmental Authority of competent jurisdiction and has not been admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise.

ARTICLE 2
LICENSE GRANTS

2.1 **Exclusive License Grant**. Subject to the terms and conditions of this Agreement, Abeona hereby grants to Ultragenyx an exclusive (even with respect to Abeona and its Affiliates, subject to Section 2.2), sublicensable (subject to Section 2.3.1), royalty-bearing right and license under the Licensed Technology, to Exploit Licensed Products in the Field and in the Territory.

2.2 **Retained Abeona Rights**. Notwithstanding the license granted to Ultragenyx pursuant to Section 2.1, Abeona will retain for itself, and its Affiliates, the right to practice the Licensed Technology solely to the extent necessary to perform any Transition Services under the Transition Plan and perform other obligations expressly set forth in this Agreement. For the avoidance of doubt, Abeona will retain the sole right to practice the Licensed Patents outside of the Field.

2.3 **Sublicensing and Subcontracting**.

2.3.1 **Ultragenyx Right to Sublicense**. Ultragenyx will have the right to grant Sublicenses (through multiple tiers) of the rights granted to Ultragenyx pursuant to Section 2.1 as follows: (a) to its Affiliates; provided such Sublicense only remains in effect for as long as such Sublicensee remains an Affiliate of Ultragenyx, and (b) to Third Parties, in each case of clause (b), subject to the requirements of Section 2.3.2.

2.3.2 **Sublicense Requirements**. Each Sublicense granted by Ultragenyx to a Third Party pursuant to Section 2.3.1 will be subject and subordinate to the terms and conditions of this Agreement. No Sublicense will materially diminish, reduce or eliminate any obligation of Ultragenyx under this Agreement. Ultragenyx will ensure that each of its non-Affiliate Sublicensees is bound by a written agreement containing provisions that are consistent with those contained in this Agreement.

2.4 **Performance by Independent Contractors**. (a) Ultragenyx may contract or delegate any portion of its obligations or activities hereunder to a Third Party contractor subject to the terms and condition of Section 14.8 and (b) Abeona may contract or delegate any portion of its obligations or activities hereunder to a Third Party contractor to the extent set forth in the Transition Plan or with the prior written authorization of Ultragenyx, in each case ((a) and (b)) provided that, (i) the contractor is appropriately qualified to conduct the activities it is engaged to conduct under this Agreement; (ii) the contractor undertakes in writing commercially reasonable obligations of confidentiality and non-use regarding Confidential Information, that are substantially the same as those undertaken by the Parties with respect to Confidential Information pursuant to ARTICLE 8 hereof (but of shorter duration if customary); and (iii) the contractor undertakes in writing to assign or exclusively license back (with the right to sublicense) all intellectual property that Ultragenyx deems to be material to the Exploitation of a Licensed Product that results from performing any such work to the corresponding Party.

2.5 **Reservation of Rights**. No rights, other than those expressly set forth in this Agreement, are granted to either Party under this Agreement, and no additional rights will be deemed granted to either Party by implication, estoppel or otherwise, with respect to any intellectual property rights. All rights not expressly granted by either Party or its Affiliates to the other Party under this Agreement are reserved. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

2.6 **Nationwide Children's Agreement**. Abeona will assign to Ultragenyx all of Abeona's right, title and interest in and to the Nationwide Children's Agreement pursuant to the terms and conditions of the Assignment Agreement. Abeona hereby covenants to Ultragenyx that, as of the Effective Date, except as provided in Paragraph 30 of the Twelfth Amendment to the Nationwide Children's Agreement, dated May 16, 2022, and solely to the extent necessary for its performance of the Transition Services, Abeona will not practice any of the intellectual property rights that are the subject of the Nationwide Children's Agreement.

2.7 **Right of First Refusal**. In the event that Abeona or any Affiliate of Abeona proposes to assign, transfer, license or otherwise grant any of Abeona's rights with respect to any Licensed Products under this Agreement to a Third Party, including Abeona's rights to receive royalties or other payments for the Commercialization of Licensed Products, but excluding any Change of Control transaction of Abeona, (such proposed transaction, a "**ROFR Transaction**") Ultragenyx will have a right of first refusal to acquire all rights related to such ROFR Transaction at a valuation, and on such additional terms and conditions, mutually agreed upon by the Parties. Abeona will provide Ultragenyx with advance written notice of the ROFR Transaction (including a summary of the material terms and conditions thereof) (a "**ROFR Notice**") and allow Ultragenyx [***] days to respond whether Ultragenyx is willing to acquire all rights relating to or subject to the ROFR Transaction from Abeona (an "**Ultragenyx Election Notice**"). Upon the receipt by Abeona of an Ultragenyx Election Notice, the Parties will negotiate in good faith for a period of [***] days (the "**ROFR Terms Negotiation Period**") to finalize the material terms and conditions regarding the acquisition by Ultragenyx of all rights related to such ROFR Transaction (the "**ROFR Term Sheet**"). If, after the completion of the ROFR Terms Negotiation Period, the Parties cannot agree upon the ROFR Term Sheet, Abeona may proceed with the ROFR Transaction as originally proposed by Abeona in the ROFR Notice, provided that if the ROFR Transaction as originally proposed is not executed within [***] days after the completion of the ROFR Terms Negotiation Period, any ROFR Transaction will again become subject to Ultragenyx's right of first refusal in accordance with this Section 2.7. If the Parties do agree upon the ROFR Term Sheet, the Parties will negotiate in good faith for a period of [***] days (the "**ROFR Negotiation Period**") to finalize and execute definitive agreements regarding the acquisition by Ultragenyx or all rights related to such ROFR Transaction. If, after the completion of the ROFR Negotiation Period, the Parties cannot agree to definitive agreements effecting the acquisition by Ultragenyx of all rights related to the ROFR Transaction, Abeona may proceed with the ROFR Transaction as originally proposed by Abeona in its written notice to Ultragenyx, provided that if the ROFR Transaction as originally proposed is not executed within [***] days after the completion of the ROFR Negotiation Period, any ROFR Transaction will again become subject to Ultragenyx's right of first refusal in accordance with this Section 2.7.

2.8 **Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement to Ultragenyx are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties agree that Ultragenyx and its Affiliates and Sublicensees will retain and may fully exercise all of its rights and elections under the Bankruptcy Code and any foreign equivalent thereto. The Parties further agree that if (a) a bankruptcy proceeding by or against Abeona or its Affiliate (the "**Bankrupt Party**") is commenced under the Bankruptcy Code, (b) this Agreement is rejected as provided in the Bankruptcy Code, and (c) Ultragenyx or its Affiliate elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, then Ultragenyx will be entitled to a complete duplicate of, and complete access to (as Ultragenyx deems appropriate), all intellectual property that is the subject of a right or license granted to Ultragenyx hereunder and all embodiments of the same. Upon such occurrence, such intellectual property and all embodiments of such intellectual property will be promptly delivered by the Bankrupt Party to Ultragenyx. The Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) hereby agrees not to interfere with the exercise by Ultragenyx of its rights or licenses to such intellectual property or such embodiments of intellectual property in accordance with this Agreement, and agrees to assist Ultragenyx and its Affiliates in obtaining such intellectual property or such embodiments of intellectual property in the possession or Control of Third Parties. The foregoing provisions are without prejudice to any rights Ultragenyx may have arising under the Bankruptcy Code or other Applicable Law. As used herein, "**Bankruptcy Code**" means Title 11, United States Code, as from time to time in effect.

ARTICLE 3
TRANSITION MATTERS; TECHNOLOGY TRANSFER

3.1 **Transition Services**.

3.1.1 **Transition Services**. During the Transition Period, Abeona (directly or through its Affiliates or approved Third Party contractors) will perform certain transition services in connection with Licensed Products ("**Transition Services**"), as more fully detailed in the Transition Plan. During the Transition Period, each Party will have the right to propose extensions of the Transition Period; provided that any proposed extension will be effective only if approved by the Alliance Manager for each Party (e-mail to be sufficient for this purpose).

3.1.2 **Transition Plan**. The initial Transition Plan is attached hereto as Schedule 3.1.2. Within [***] days following the Effective Date, the Parties will update the Transition Plan. Each such plan, as modified, will include (a) a description of the Transition Services, (b) the proposed timetable for performing such Transition Services, (c) the estimated Transition Costs for completion of such Transition Services (attached separately as Schedule 3.1.4), (d) the deliverables, (e) the name of any Third Party contractors engaged by Abeona for the performance of the Transition Services and a description of which activities such contractors will perform and (f) such other information agreed upon by the Parties (the plan attached hereto as Schedule 3.1.2 and each update thereto in accordance with this Agreement, the "**Transition Plan**"). Abeona will use Commercially Reasonable Efforts to complete the Transition Services assigned to Abeona within the timeframes set forth in the Transition Plan and within the estimated Transition Costs. In the event of any inconsistency between the Transition Plan and this Agreement, the terms of this Agreement will prevail. During the Transition Period, each Party will have the right to propose modifications or amendments to the Transition Plan; provided, however that any modifications or amendments to such Transition Plan that are proposed by either Party will be subject to review and approval by the Joint Transition Team pursuant to Section 5.1.2.

3.1.3 **Transition Services Reporting**. At each meeting of the Joint Transition Team, Abeona will provide an update regarding the Transition Services it has performed, or caused to be performed, since the previous meeting of the Joint Transition Team, its Transition Services in process, and the future Transition Services it expects to initiate prior to the next meeting of the Joint Transition Team. Abeona will highlight any key issues or delays with respect to the Transition Services or any expected issues related to the Transition Costs for joint discussion and resolution. Abeona will respond to the questions or requests of the Joint Transition Team or Ultragenyx, as applicable, for additional information relating to such Transition Services in a timely manner.

3.1.4 **Transition Services Costs**. Ultragenyx will reimburse Abeona for Transition Costs in accordance with Schedule 3.1.4, including incurred Transition Costs up to [***] percent ([***]%) of the amount included in the then-current Schedule 3.1.4. If Abeona believes that Transition Costs are likely to exceed [***] percent ([***]%) of the amount included in the then-current Schedule 3.1.4, Abeona will promptly revise the Transition Costs and submit it in writing, with an explanation of the variance and the reasons therefor, simultaneously to the JTT and the Executive Officers. If the Executive Officers or their designees unanimously approve of the revised Schedule 3.1.4 then such revised Transition Costs will be deemed incorporated into the Transition Plan and if the Executive Officers or their designees do not unanimously approve of the revised Schedule 3.1.4 then Abeona shall be relieved of providing additional Transition Services.

3.2 **Transfer of Licensed Know-How**. Promptly following the Effective Date (but in any event within [***] days thereof), Abeona will, and will cause its Affiliates and contractors to, transfer to Ultragenyx or its designee the Know-How forth on Schedule 3.2. In addition, Abeona will disclose and make available to Ultragenyx additional Licensed Know-How that exists as of the Effective Date pursuant to and within the timeframes set forth in the Transition Plan. Following the Transition Period and throughout the Term, Abeona will disclose and make available to Ultragenyx any additional Licensed Know-How of which Abeona or Ultragenyx becomes aware and respond to any requests by Ultragenyx for additional Licensed Know-How.

3.3 **Manufacturing Technology Transfer; Assignment of Inventory**. Within [***] days of the Effective Date, Abeona will transfer to Ultragenyx or its designee in an orderly manner, (a) copies of all data, information, and other Know-How, including Materials, Controlled by Abeona or its Affiliates and (b) all data, information and other Know-How, including Materials, Controlled by any Existing Vendor or other (sub)contractor of Abeona or its Affiliates, in each case ((a) and(b)), that are necessary or reasonably useful to enable Ultragenyx and its designees to Manufacture each Licensed Product. Abeona hereby assigns to Ultragenyx all of Abeona's right, title and interest in and to the Inventory.

3.4 **Assignment of Existing Vendor Agreements**. At any time during the Transition Period, upon Ultragenyx's request, Abeona will: (a) assign, or cause its Affiliates to assign, to Ultragenyx or its designee any of the Existing Vendor Agreements, if Abeona is permitted to make such assignment under the terms of the Existing Vendor Agreement; or (b) reasonably assist Ultragenyx or its Affiliate in entering into new agreements directly with the counterparties to any of the Existing Vendor Agreements to cover the subject matter related to the Licensed Products, as applicable. Each such assignment under this Section 3.4 will include the assignment to Ultragenyx of any pre-paid positions or credits in favor of Abeona or its Affiliate under the corresponding Existing Vendor Agreement.

3.5 **Ongoing Abeona Assistance**. During the Term, in addition to the Transition Services, Abeona will reasonably cooperate with and provide information and assistance to Ultragenyx or its designee, at Ultragenyx's cost, through documentation, consultation, and face-to-face meetings, in connection with the exercise of the licenses and rights granted to Ultragenyx, its Affiliates and Sublicensees under this Agreement, including as useful or necessary to enable Ultragenyx or its designees, to proceed with Exploitation of the Licensed Products and to obtain all appropriate Regulatory Approvals for the Licensed Products in an efficient and timely manner. In furtherance of the foregoing, if requested by Ultragenyx, Abeona will provide Ultragenyx and its designees with reasonable and timely access to qualified Abeona personnel (and personnel of its Affiliates and Third Party contractors) involved in Development or Manufacturing matters related to the Licensed Products, to assist in transferring data, information, and other Know-How to Ultragenyx or its designee; provided, that such assistance will not exceed [***] hours in a given Calendar Year and Abeona's obligations under this Section 3.5 will expire on September 30, 2023.

3.6 **Spain Entity**. Upon the written request of Ultragenyx, such request to be made (if at all) during the Transition Period, the Parties will negotiate in good faith the sale by Abeona, and purchase by Ultragenyx, of Abeona Therapeutics Europe, S.L., without additional consideration.

ARTICLE 4
DEVELOPMENT, REGULATORY, MANUFACTURE AND COMMERCIALIZATION

4.1 **Development Activities**.

4.1.1 **Development Responsibilities and Compliance**. Subject to the terms and conditions of this Agreement, Ultragenyx will be solely responsible for managing and performing all activities relating to the Development of each Licensed Product, including obtaining and maintaining Regulatory Approval in the Field and in the Territory, except for such Development activities performed by Abeona (directly, or through its Affiliates or permitted Third Party contractors) as part of the Transition Services.

4.1.2 **Development Diligence**. Subject to the terms and conditions of this Agreement, Ultragenyx (directly, or through its Affiliates, Sublicensees or contractors) will use Commercially Reasonable Efforts to Develop at least one Licensed Product in the Field in the Territory. Ultragenyx will not be deemed to be in breach of its obligations under this Section 4.1 to the extent it is prevented from or delayed in using Commercially Reasonable Efforts to Develop a Licensed Product as a result of the acts or omissions of Abeona.

4.1.3 **Development Costs**. Ultragenyx will have sole responsibility for (a) all External Costs and FTE Costs incurred by or on behalf of Ultragenyx related to the Development of each Licensed Product during the Term and (b) the Prior Development Costs incurred by or on behalf of Abeona during the period of time beginning on March 15, 2022 and ending on the Effective Date, as set forth on Schedule 4.1.3. In no event will Ultragenyx have any responsibility for costs incurred by Abeona prior to March 15, 2022, which will be borne solely by Abeona even if any such costs are invoiced on or after March 15, 2022. Without limiting the foregoing, Abeona's obligations under this Section 4.1.3 include the obligation to pay any costs under the Nationwide Children's Agreement that accrued prior to March 15, 2022 and if Ultragenyx pays Nationwide Children's any such costs under the Nationwide Children's Agreement, then Abeona will promptly reimburse Ultragenyx for the same.

4.2 **Regulatory Submissions and Approvals**.

4.2.1 **Regulatory Responsibilities**.

(a) During the Transition Period, to the extent set forth in the Transition Plan, the Transition Services may include preparing and submitting Regulatory Materials and otherwise with respect to obtaining Regulatory Approvals for the Licensed Products and in the activities in support thereof. Abeona will perform any such Transition Services in accordance with the Transition Plan. Abeona will provide any Regulatory Materials to be filed or submitted by Abeona with respect to any Licensed Product, including any draft correspondence or communication with Regulatory Authorities, to Ultragenyx, and, for the avoidance of doubt, will not file or submit any Regulatory Materials (or convey any such correspondence or communication to any Regulatory Authority) with respect to any Licensed Product without prior written approval by Ultragenyx.

(b) Ultragenyx will have the sole right, and will use Commercially Reasonable Efforts, itself or with or through its Affiliates, Sublicensees, or other Third Parties, to: (a) prepare and submit to applicable Regulatory Authorities all Regulatory Materials for the Licensed Products; and (b) obtain and maintain all Regulatory Approval and Pricing and Reimbursement Approval for the Licensed Products at Ultragenyx's sole cost and expense.

4.2.2 **Communications with Regulatory Authorities**. Except as set forth in Section 4.2.1(a), as between the Parties, Ultragenyx will have the sole right to correspond or communicate with Regulatory Authorities regarding the Licensed Products during the Term and, upon the reasonable request of Ultragenyx, Abeona will, at Ultragenyx's cost, support Ultragenyx with respect to such activities. For clarity, unless required by Applicable Law, Abeona, its Affiliates, and its permitted subcontractors will not correspond or communicate with Regulatory Authorities regarding any Licensed Product without first obtaining Ultragenyx's prior written consent. If Abeona, any of its Affiliates, or any of its permitted subcontractors receives any correspondence or other communication from a Regulatory Authority regarding a Licensed Product, then Abeona will promptly provide Ultragenyx with access to or copies of all such material written or electronic correspondence promptly after its receipt.

4.2.3 **Ownership of Regulatory Approvals**. Ultragenyx will own all Regulatory Materials, including all submissions and applications for Regulatory Approvals, and Regulatory Approvals, for the Licensed Products in the Field in the Territory. Abeona hereby assigns and transfers to Ultragenyx (or its designee), and will cause its Affiliates to assign or transfer, any and all such Regulatory Materials. Within [***] days after the Effective Date, Abeona will provide to Ultragenyx true, accurate, and complete electronic copies, and hard copies, to the extent they exist as of the Effective Date and are not duplicative of such electronic copies thereof (taking into consideration the legibility of such electronic copies).

4.2.4 **Right of Reference to Regulatory Materials**. For any Regulatory Materials Controlled by Abeona or its Affiliates that are not timely assigned and transferred in accordance with Section 4.2.4, Abeona will and hereby does grant to Ultragenyx a "Right of Reference," (as defined in 21 C.F.R. § 314.3(b) as applied to an IND or BLA (or any successor rule), or similar "right of reference" as defined in applicable regulations in the relevant jurisdiction), to, and a right to copy, access, and otherwise use, all information and data included in any Regulatory Materials that are Controlled by Abeona or its Affiliates to the extent necessary or reasonably useful to assist Ultragenyx in obtaining Regulatory Approval for any Licensed Product in the Field. Abeona will provide a signed statement to this effect, if requested by Ultragenyx, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Applicable Law recognized outside of the United States).

4.2.5 **Regulatory Cooperation**. Notwithstanding Section 3.5, Abeona will provide reasonable cooperation and support to Ultragenyx, at Ultragenyx's cost, in preparing and submitting Regulatory Materials and obtaining Regulatory Approvals for each Licensed Product and in the activities in support thereof.

4.3 **Manufacturing Activities**. Ultragenyx, its Affiliates, its or their Sublicensees or subcontractors will be solely responsible, at Ultragenyx's sole cost and expense, for Manufacturing and supplying requirements for the Development and Commercialization of the Licensed Products in the Territory, except for such Manufacturing activities performed by Abeona (directly, or through its Affiliates or permitted Third Party contractors) as part of the Transition Services.

4.4 **Commercialization**. Upon receipt of the Regulatory Approval for a Licensed Product in the Field in a given country in the Territory, Ultragenyx (directly, or through its Affiliates, its or their Sublicensees or subcontractors) will use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Field in such country in the Territory. As between the Parties, Ultragenyx will be solely responsible for and will have sole discretion with respect to, Commercializing each of the Licensed Products in the Field in the Territory, including development and implementation of any promotional or branding strategy and materials, handling all returns, recalls, order processing, booking sales, invoicing and collections, inventory and receivables, and price matters.

4.5 **Development and Commercialization Reporting**. Beginning on March 31 of the Calendar Year following the end of the Transition Period, and on each such anniversary thereafter prior to the date on which the first report is due under Section 6.5, Ultragenyx will submit to Abeona a written report summarizing Ultragenyx's material Development and Commercialization activities with respect to the Licensed Products pursuant to this Agreement since the date of Ultragenyx's delivery of the prior report, and, with respect to the first of such reports, since the Effective Date.

ARTICLE 5
JOINT TRANSITION TEAM

5.1 **Joint Transition Team**.

5.1.1 **Formation; Purposes and Principles**. Within [***] days after the Effective Date, Abeona and Ultragenyx will form a core team (the "**Joint Transition Team**" or "**JTT**") to facilitate information sharing between the Parties with respect to the Development of the Licensed Products. The Joint Transition Team will be a discussion body only and will not have decision-making power.

5.1.2 **Specific Responsibilities**. In addition to its overall responsibility to facilitate information sharing between the Parties with respect to the Development activities under this Agreement, the Joint Transition Team will:

(a) review and discuss proposed amendments or revisions to the Transition Plan or Transition Costs(for clarity, Ultragenyx will have the final decision making authority to approve the Transition Plan as described in Section 3.1.2; provided that (i) any amendment or revision to add additional material obligations that are not set forth in the Transition Plan will require Abeona's consent, (ii) any reduction in the Transition Costs without a corresponding decrease in activities under the Transition Plan will require Abeona's consent, and (iii) any proposed increase in the Transition Costs will be subject to Section 3.1.4);

(b) exchange information with respect to the Transition Services, and review and discuss Abeona's activities and progress under the Transition Plan;

(c) discuss and attempt to resolve any issues related to the Transition Plan;

(d) discuss the transfer of Licensed Know-How and serve as a forum for Abeona to answer questions with respect to such Licensed Know-How;

(e) exchange information with respect to the Development of Licensed Products;

(f) exchange information with respect to Abeona's ongoing support obligations under Section 3.5; and

(g) perform such other functions as are assigned to it in this Agreement or as appropriate to further the purposes of this Agreement to the extent agreed to in writing by the Parties.

5.1.3 **Membership**. The Joint Transition Team will be composed of representatives of each Party; provided that neither Party may appoint more than [***] representatives to the Joint Transition Team. In accordance with the foregoing, each Party will appoint members to the Joint Transition Team. Each individual appointed by a Party as a representative to the Joint Transition Team will be an employee or consultant (provided that any such consultant is under obligations of confidentiality and non-use with respect to the Confidential Information of each Party in keeping with Section 8.1) of such Party with sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the Joint Transition Team's responsibilities, and have knowledge and expertise in the Development of products similar to the Licensed Products under this Agreement. Each Party may replace any of its Joint Transition Team representatives at any time upon written notice to the other Party, which notice may be given by e-mail, sent to the other Party. The Joint Transition Team will be co-chaired by one designated representative of each Party. Each Joint Transition Team representative and the Alliance Manager (as defined in Section 5.2) will be subject to confidentiality obligations no less stringent than those in ARTICLE 8.

5.1.4 **Meetings**. The Joint Transition Team will hold meetings at least [***] per [***] during the Transition Period, with the option to hold additional meetings on an ad hoc basis. Prior to any meeting of the Joint Transition Team an agenda for such meeting will be prepared and circulated by the Alliance Managers. Either Party may also call a special meeting of the Joint Transition Team by providing reasonable prior written notice (e-mail to the other Party's Alliance Manager will suffice) to the other Party. The Joint Transition Team may meet in person or by audio or video conference as its representatives may mutually agree. Other representatives of the Parties, their Affiliates and Third Parties involved in the Development of Licensed Products may be invited by the members of the Joint Transition Team to attend meetings as observers or to facilitate discussions outside of meetings; provided, however, that such representatives are subject to confidentiality obligations no less stringent than those set forth in ARTICLE 8. The minutes of each Joint Transition Team meeting will be prepared and circulated in accordance with the procedures established by the Joint Transition Team. Each Party will be responsible for its costs to attend each meeting of the Joint Transition Team.

5.1.5 **Sub-teams**. From time to time, the Joint Transition Team may establish sub-teams, as it deems necessary or advisable to further the purposes of this Agreement, including any responsibilities assigned to the Joint Transition Team under this Agreement; provided, however, that no sub-team will have any power to amend, modify or waive compliance with this Agreement. Each sub-team will consist of [***] number of representatives of each Party (unless otherwise agreed by the Parties) and meet with such frequency as the Joint Transition Team determines is appropriate from time to time. The purpose, scope and procedures of any such sub-team will be mutually agreed by the Parties.

5.1.6 **Disbanding of Joint Transition Team**. Unless otherwise agreed by the Parties, the Joint Transition Team will have no further responsibilities and will automatically disband upon expiration of the Transition Period.

5.2 **Alliance Managers**. Promptly after the Effective Date, each Party will appoint an individual to act as alliance manager for such Party (each, an "**Alliance Manager**"). The Alliance Managers will be the primary point of contact for the Parties regarding communications contemplated by this Agreement, whether formal reporting obligations or otherwise, including after disbanding of the Joint Transition Team. The Alliance Managers will also be responsible for assisting the Joint Transition Team in performing its responsibilities such as scheduling meetings, circulating agendas as necessary and preparing and finalizing the minutes from meetings of the Joint Transition Team. Each Party may replace its Alliance Manager, in its sole discretion, from time to time, upon notification to the other Party, which notice may be given by e-mail, sent to the other Party's Alliance Manager.

ARTICLE 6
FINANCIAL PROVISIONS

6.1 **Prior Development Costs**. Ultragenyx will pay the Prior Development Costs in accordance with Section 6.7.

6.2 **Milestone Payments**.

6.2.1 **Commercial Milestones**. During the Term, Ultragenyx will pay Abeona the milestone payments set forth in this Section 6.2.1 (each, a "**Milestone Payment**") upon the achievement of the relevant milestone event with respect to the Licensed Products (each, a "**Milestone Event**"), subject to the limitations set forth in this Section 6.2.1. Each of the Milestone Payments is payable only upon the first achievement of such Milestone Event and none of the Milestone Payments will be payable more than once and no amounts will be due for subsequent or repeated achievements of such Milestone Event. For clarity, the Milestone Payments will be additive such that if both Milestone Events set forth below are achieved in the same Calendar Year, Ultragenyx will pay to Abeona a payment of Thirty Million Dollars ($30,000,000), and the maximum aggregate amount of Milestone Payments payable by Ultragenyx pursuant to this Section 6.2.1 is Thirty Million Dollars ($30,000,000).

Milestone Event	Milestone Payment (in Dollars)	
1. Aggregate annual Net Sales of all Licensed Products in the Territory in a Calendar Year are greater than [***] Dollars ($[***])	$	[***]
2. Aggregate annual Net Sales of all Licensed Products in the Territory in a Calendar Year are greater than [***] Dollars ($[***])	$	[***]
Total	**$**	**30,000,000**

6.2.2 **Notice; Payment**. Each Milestone Payment will be deemed earned upon achievement of the corresponding Milestone Event, and Ultragenyx will provide Abeona with written notice of the achievement of each of the Milestone Events set forth in Section 6.2.1 within [***] days after the end of the Calendar Year in which such Milestone Event is first achieved. Ultragenyx will pay to Abeona the applicable Milestone Payment within [***] days of receipt of Abeona's invoice therefor, such invoice to be issued after receipt of notice from Ultragenyx under this Section 6.2.2.

6.3 **Royalties**.

6.3.1 **Royalty Rate**. Subject to the terms and conditions of this Agreement, and in partial consideration for the rights granted to Ultragenyx under this Agreement, during the Royalty Term, Ultragenyx will pay to Abeona non-refundable, non-creditable royalties (except in the case of an overpayment as set forth in Section 6.9.2) at the graduated royalty rates specified in the applicable table set forth in either (a) or (b) below with respect to the aggregate annual worldwide Net Sales of all Licensed Products sold by a Selling Party in the Territory in a given Calendar Year:

(a) Royalties on Licensed Products if FDA approval of a BLA for the first Licensed Product in the Field is received by Ultragenyx on or before [***]:

Aggregate Annual Worldwide Net Sales of all Licensed Products in a Calendar Year	**Royalty Rate**
Portion of aggregate annual worldwide Net Sales up to and including [***] Dollars ($[***])	[***] percent ([***]%)
Portion of aggregate annual worldwide Net Sales greater than [***] Dollars ($[***]) up to and including [***] Dollars ($[***])	[***] percent ([***]%)
Portion of aggregate annual worldwide Net Sales greater than [***] Dollars ($[***])	Ten percent (10%)

(b) Royalties on Licensed Products if FDA approval of a BLA for the first Licensed Product in the Field is not received by Ultragenyx on or before [***]:

Aggregate Annual Worldwide Net Sales of all Licensed Products in a Calendar Year	**Royalty Rate**
Portion of aggregate annual worldwide Net Sales up to and including [***] Dollars ($[***])	[***] percent ([***]%)
Portion of aggregate annual worldwide Net Sales greater than [***] Dollars ($[***]) up to and including [***] Dollars ($[***])	[***] percent ([***]%)
Portion of aggregate annual worldwide Net Sales greater than [***] Dollars ($[***])	[***] percent ([***]%)

6.3.2 **Royalty Term**. Royalties will be due under this Section 6.3 with respect to a given Licensed Product only during the Royalty Term.

6.3.3 **Only One Royalty**. The obligation to pay royalties will be imposed only once with respect to the same unit of a Licensed Product even if the manufacture, use or sale of such Licensed Product is covered by more than one of the Licensed Patents.

6.4 **Royalty Payment Reductions**. The royalties payable under Section 6.2.2 will be subject to the following:

6.4.1 **Third Party Licenses**. In the event that Ultragenyx identifies any Patent or Know-How Controlled by a Third Party in a particular country or other jurisdiction that, absent a license or agreement with such Third Party, would be infringed by Exploiting a Licensed Product in the Field in the Territory ("**Blocking IP**"), Ultragenyx or any of its Affiliates will have the right, but not the obligation, to enter into an agreement with a Third Party to acquire or obtain a license, covenant not to sue or other similar right to any Blocking IP (such agreement, a "**Third Party License**"). If Ultragenyx or any of its Affiliates enters into a Third Party License, Ultragenyx will be entitled to deduct from payments due under Section 6.3 [***] percent ([***]%) of all upfront payments, milestone payments, royalties, fees or any other amounts or consideration paid to such Third Party in respect of such Third Party License to the extent related to the Licensed Products, including the Exploitation thereof; provided that (a) such offset will not decrease any particular payment due under Section 6.3 by more than [***] percent ([***]%); and (b) any such deductions not fully taken as a result of the application of the foregoing clause (a) may be carried forward by Ultragenyx to reduce subsequent amounts due under Section 6.3 until all such deductions are fully taken. Abeona hereby covenants that it will not, and will cause its Affiliates not to, negotiate or enter into any Third Party License specific to the Exploitation of a Licensed Product or specific to the Exploitation of a product in the Field.

6.4.2 **Lack of Patent Protection and Regulatory Exclusivity**. Subject to 6.4.4, the royalties payable to Abeona with respect to Net Sales of Licensed Products will be reduced, on a Licensed Product–by–Licensed Product and country-by-country basis, to [***] percent ([***]%) of the amounts otherwise payable pursuant to Section 6.3.1 during any portion of the Royalty Term upon the later of (a) expiration of the last-to-expire Valid Claim Covering the applicable Licensed Product in such country, or at the time of First Commercial Sale in such country if no such Valid Claim exists in such country at such time, and (b) expiration of Regulatory Exclusivity for such Licensed Product in such country, or at the time of First Commercial Sale in such country if no such Regulatory Exclusivity exists in such country at such time.

6.4.3 **Biosimilar Competition**. If, on a Licensed Product-by-Licensed Product and country-by-country basis, at least one Biosimilar Product is commercially available with respect to such Licensed Product in such country and the combined market share for all such Biosimilar Products is (i) greater than [***] percent ([***]%) but no greater than [***] percent ([***]%) of the total market (i.e., the total number of units for such Biosimilar Product(s) and Licensed Product), then the royalties on Net Sales of such Licensed Product in such country will be reduced by [***] percent ([***]%) as of the Calendar Quarter in which such Biosimilar Product(s) obtain such combined market share, or (ii) greater than [***] percent ([***]%) of the total market (i.e., the total number of units for such Biosimilar Product(s) and Licensed Product), then the royalties on Net Sales of such Licensed Product in such country will be reduced by [***] percent ([***]%) as of the Calendar Quarter in which such Biosimilar Product(s) maintain such combined market share. Unit volume sales will be identified and calculated based on relevant information published by IQVIA, any successor to IQVIA, or any other similar industry-standard Third Party source used by Ultragenyx.

6.4.4 **Cumulative Deductions**. Notwithstanding the foregoing, in no event will the deductions set forth in Section 6.4.1 through Section 6.4.3 reduce any royalty payment that is payable to Abeona as specified in Section 6.3.1 by more than [***] percent ([***]%).

6.5 **Royalty Payments and Reports**. Within [***] days after the end of each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of a Licensed Product is made anywhere in the Territory, Ultragenyx will provide to Abeona a report setting forth on a Licensed Product–by–Licensed Product and country-by-country basis (a) the Net Sales; and (b) the calculation of the royalties payable under this Agreement on account of those Net Sales. Each royalty report along with the royalties shown to have accrued on that report are due and payable to Abeona within [***] days following the end of such Calendar Quarter. All payments due under this Section 6.5 will be made by bank wire transfer or ACH payment in immediately available funds to an account designated by Abeona.

6.6 **Invoicing for Additional Amounts**. With respect to any amounts owed under this Agreement by one Party to the other Party for which no other invoicing or payment procedure is specified elsewhere in this Agreement, within [***] days after the end of each Calendar Quarter, the applicable Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed that were incurred or accrued during such Calendar Quarter. The owing Party will pay any undisputed amounts within [***] days of receipt of the invoice, and any disputed amounts owed by the owing Party will be paid within [***] days of resolution of the Dispute.

6.7 **Reimbursement of Prior Development Costs and Transition Costs**. Ultragenyx will reimburse Abeona for the Prior Development Costs and Transition Costs actually incurred by Abeona or its Affiliates for the Transition Services in accordance with the Transition Plan (subject to Section 3.1.4). Abeona will provide an invoice for the Prior Development Costs and Transition Costs each month in arrears, and any payments to be made to Abeona by Ultragenyx pursuant to this Section 6.7 will be made within [***] days of receipt of invoices submitted by Abeona to Ultragenyx. Each such invoice will be accompanied by reasonable supporting documentation. Payment for Transition Costs will not exceed the amounts calculated in accordance with Section 3.1.4.

6.8 **Costs**. Except as otherwise set forth herein, each Party will bear its own costs incurred under this Agreement.

6.9 **Financial Audits**.

6.9.1 **Record Keeping**. Ultragenyx and its Affiliates will, and will cause their respective Sublicensees to, keep complete, true and accurate books and records in accordance with its Accounting Standards of the items underlying (a) Net Sales, and (b) royalty payments under this Agreement. Ultragenyx and its Affiliates will, and will cause their respective Sublicensees to keep, such books and records for at least [***] years following the Calendar Quarter to which they pertain. Abeona will have the right annually, at its own expense, to have an internationally-recognized independent, certified public accountant, selected by Abeona and reasonably acceptable to Ultragenyx (the "**Auditor**"), review any such records of Ultragenyx in the location(s) where such records are customarily maintained by Ultragenyx upon at least [***] days' prior written notice, during regular business hours and under obligations of confidentiality, except to the extent necessary to enforce Abeona's rights under this Agreement or if disclosure is required by Applicable Law, for the sole purpose of verifying the basis and accuracy of payments made under this Agreement and the content of the reports described in Section 6.5, within the prior [***] Calendar Year period after receipt of such report. The Auditor will have the right to disclose to Abeona its conclusions regarding any payment owed under this Agreement. The records for any Calendar Year may be audited no more than once with respect to records covering any specific period of time.

6.9.2 **Audit Report**. The report prepared by the Auditor, a copy of which will be sent or otherwise provided to each Party by such Auditor at the same time before such report is considered final, will contain the conclusions of such Auditor regarding the audit and will specify that the amounts paid pursuant thereto were correct or, if incorrect, the amount of any underpayment or overpayment, and the specific details regarding any discrepancies. No other information will be provided to Abeona without the prior consent of Ultragenyx unless disclosure is required by Applicable Laws and if so determined by Abeona in consultation with Ultragenyx, it will, if permitted, give Ultragenyx prior notice thereof to the extent possible for Ultragenyx to seek a protective order against or limiting such disclosure. If such report shows any underpayment, then Ultragenyx will remit to Abeona, within [***] days after receipt of such report, (a) the amount of such underpayment and (b) if such underpayment exceeds [***] percent ([***]%) of the total amount owed for the period then being audited, the actual auditor costs incurred by Abeona in conducting such review. For the avoidance of doubt, payment of the underpayment will be considered a late payment, subject to Section 6.13. If such report shows any overpayment, then at Ultragenyx's election, either Ultragenyx will deduct the overpaid amount for application against future payments owed to Abeona or Abeona will reimburse Ultragenyx the amount of such overpayment. The Parties mutually agree that all information subject to review under this Section 6.9 is Confidential Information of Ultragenyx, and that Abeona will cause the Auditor to retain all such information in confidence in accordance with confidentiality and non-use obligations no less stringent than those contained in ARTICLE 8. Notwithstanding the foregoing, if Ultragenyx challenges the results of the audit in good faith, Ultragenyx will be entitled at its own cost and expense to obtain a second independent certified public accountant to confirm the accuracy of the first audit. If the results of such confirmatory audit are within [***] percent ([***]%) of the results of the first audit, any amounts owed or overpaid by Ultragenyx will be paid or refunded in accordance with the procedures above. If the results of such confirmatory audit are not substantially similar to the results of the first audit, each Party shall cause its respective auditors to identify the discrepancy and to agree on a final amount owed or overpaid (as the case may be) by Ultragenyx that shall be final and binding on the Parties.

6.10 **Withholding Taxes**. Ultragenyx may withhold from payments due to Abeona amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority with respect to such payments. Ultragenyx will provide Abeona all relevant documents and correspondence, and will also provide to Abeona any other cooperation or assistance on a reasonable basis as may be necessary to enable Abeona to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Ultragenyx will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include Ultragenyx making payments from a single source in the U.S., where possible.

6.11 **Blocked Payments**. In the event that, by reason of Applicable Law in any country, it becomes impossible or illegal for Ultragenyx to transfer, or have transferred on its behalf, payments owed Abeona hereunder, Ultragenyx will promptly notify Abeona of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Abeona in a recognized banking institution designated by Abeona or, if none is designated by Abeona within a period of [***] days, in a recognized banking institution selected by Ultragenyx, as the case may be, and identified in a written notice given to Abeona.

6.12 **Manner of Payments; Currency**. All payments to be made by Ultragenyx hereunder will be made in Dollars by wire transfer to such bank account as Abeona may designate. For any currency conversion from the currency of one country in which the Licensed Products are sold into U.S. Dollars (or another currency if applicable) required in determining the amount of Net Sales or any royalties or revenue share due hereunder, such conversion will be equal to the average exchange rate, over the applicable Calendar Quarter, calculated at the conversion rate as reported by OANDA (www.oanda.com), or an equivalent or similar resource as agreed by the Parties, on the last Business Day of the Calendar Quarter in which the applicable Net Sales were made.

6.13 **Late Payments**. Without limiting any other rights or remedies available to Abeona hereunder, any undisputed late payment or portion thereof by Ultragenyx will bear interest, to the extent permitted by Applicable Law, at an annual rate of [***] percent ([***]%) above the applicable daily rate published in the Wall Street Journal (or any other qualified source that is acceptable to both Parties) on the date payment was due or the highest rate permitted by Applicable Law (whichever is lower), computed from the date such payment was due until the date Ultragenyx makes the payment. Where the late payment is caused by Abeona, including for reasons such as failure to communicate in a timely manner changes to bank details, or failure to respond to communications from Ultragenyx regarding the interpretation or dispute of the terms of such payment, then no interest will be payable by Ultragenyx.

ARTICLE 7
INTELLECTUAL PROPERTY OWNERSHIP, PROTECTION AND RELATED MATTERS

7.1 **Ownership**.

7.1.1 **Pre-Existing IP**. Subject only to the rights expressly granted to the other Party under this Agreement, each Party will retain all rights, title, and interests in and to all Patents, Know-How and other intellectual property rights that are owned, licensed, or sublicensed by such Party prior to or independent of this Agreement.

7.1.2 **Sole Inventions**. Except as set forth in this Section 7.1.2, as between the Parties, each Party will own all inventions and Know-How that are conceived, discovered, developed or otherwise made, as necessary to establish authorship (in case of publication and other copyrightable work), inventorship (in case of inventions, whether patentable or not) or ownership under Applicable Law, solely by or on behalf of such Party (or its Affiliates, its or their subcontractors or sublicensees (including Sublicensees) or its or their respective directors, officers, employees or agents) in the course of performing such Party's activities or exercising such Party's rights under this Agreement, and any and all Patents and other intellectual property rights thereto (collectively, "**Sole Inventions**"). As between the Parties, (a) Ultragenyx will own all inventions and Know-How that are conceived, discovered, developed or otherwise made (i) solely by or on behalf of Ultragenyx or (ii) solely by or on behalf of Abeona or jointly by or on behalf of each Party in the performance of the Transition Services that, in the case of (ii), constitute an improvement or modification of a Licensed Product or improvement or modification to any Know-How or Patents that relate to a product in the Field that are Controlled by Ultragenyx (collectively, ((i) and (ii)), "**Ultragenyx Sole Inventions**"), and (b) Abeona will own all inventions and Know-How that are conceived, discovered, developed or otherwise made solely by or on behalf of Abeona (i) outside of the performance of the Transition Services or (ii) solely by or on behalf of Abeona in the performance of the Transition Services that do not constitute an Ultragenyx Sole Invention as described in clause (a)(ii) of the definition of Ultragenyx Sole Inventions ("**Abeona Sole Inventions**"). All Patents claiming patentable Ultragenyx Sole Inventions will be referred to herein as "**Ultragenyx Patents**". All Patents claiming patentable Abeona Sole Inventions described in clause (ii) of the definition of Abeona Sole Inventions are hereby deemed Licensed Patents and all Know-How that is an Abeona Sole Invention described in such clause (ii) is hereby deemed Licensed Know-How. Abeona hereby assigns, and agrees to assign, to Ultragenyx all right, title and interest in and to the Ultragenyx Sole Inventions that are described in clause (a)(ii) of the definition of Ultragenyx Sole Inventions.

7.1.3 **Joint Inventions**. As between the Parties, except for any Ultragenyx Sole Inventions described in clause (a)(ii) of Section 7.1.2, each Party will own an equal, undivided interest in all inventions and Know-How that are conceived, discovered, developed or otherwise made, as necessary to establish authorship (in case of publication and other copyrightable work), inventorship (in case of inventions, whether patentable or not) or ownership under Applicable Law, jointly by or on behalf of each Party (or their respective Affiliates, subcontractors or sublicensees (including Sublicensees) or its or their respective directors, officers, employees or agents) in the course of performing activities or exercising rights under this Agreement during the Transition Period (collectively, "**Joint Inventions**"), and any and all Joint Patents and other intellectual property rights thereto. Each Party will have full rights to license, assign and exploit such Party's interest in such Joint Inventions (and any Joint Patents arising therefrom) anywhere in the world, without any requirement of gaining the consent of, or accounting to, the other Party, subject to the licenses granted herein and subject to any other intellectual property held by such other Party. Each Party will promptly disclose to the other all Joint Inventions, in each case, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates' subcontractors or sublicensees (including Sublicensees') or its or their directors, officers, employees or agents, describing such Joint Inventions.

7.1.4 **Assignment Obligation**. Each Party will cause all employees of such Party who perform activities for such Party under this Agreement to be under an obligation to assign their rights prior to performing any such activities, in any Patents and Know-How, whether or not patentable, resulting therefrom to such Party to effectuate the terms and conditions set forth in this Section 7.1. With respect to any activities of a Party under this Agreement that are subcontracted to a Person that is not an employee, the Party retaining such subcontractor will include in the applicable subcontract an assignment to such Party of all rights in Patents and Know-How made by such subcontractor resulting from such activities, and in any event will include in the applicable subcontract a license to such Party that is fully sublicensable to the other Party under this Agreement and comports with the scope of the licenses granted hereunder, of any Patents and Know-How made by such subcontractor resulting from such activities.

7.1.5 **Inventorship**. Inventorship for inventions made during the course of the performance of this Agreement will be determined in accordance with United States patent laws for determining inventorship.

7.2 **Prosecution and Maintenance of Patents**.

7.2.1 **Prosecution of Licensed Patents**. As between the Parties, Abeona will have the sole right, but not the obligation, to Prosecute the Licensed Patents in the Field in the Territory at Abeona's sole cost and expense through patent counsel or agents of its choice. In no event will Ultragenyx, itself or in coordination with an Affiliate or Third Party, (a) Prosecute any Licensed Patent or (b) have step-in rights with respect to the Prosecution of any of the Licensed Patents.

7.2.2 **Cooperation in Prosecution**. Neither Ultragenyx nor its Affiliates will have any obligation to cooperate with Abeona with respect to the Prosecution of Licensed Patents pursuant to this Section 7.2.

7.2.3 **Prosecution of Ultragenyx Patents**. Ultragenyx will control and be responsible, at its own expense, for the Prosecution of all Ultragenyx Patents.

7.2.4 **Patent Extensions; Data Exclusivity and Purple Book and Patent Register Listings; Biosimilar Applications**.

(a) **Patent Term Extension**. If elections with respect to obtaining patent term extension or supplemental protection certificates or their equivalents in any country with respect to any Licensed Product become available, then, as between the Parties, Ultragenyx will have the sole right to determine which Joint Patent, if any, to extend. Ultragenyx shall have no right to extend the term of a Licensed Patent without Abeona's express written consent.

(b) **Purple Book and Patent Register Listings**. Ultragenyx has the sole discretion to determine whether to list or de-list any Licensed Patents or Joint Patents, if any, with the applicable Regulatory Authorities for any Licensed Product, including the FDA's Purple Book and all other so-called "Patent Register" listings required by certain Governmental Authorities, and all similar listings in any other relevant countries. To the extent that Ultragenyx elects to list a Licensed Patent or Joint Patent in the Purple Book or any foreign equivalents with respect to a Licensed Product, Ultragenyx will have the sole right to make all applicable filings with Regulatory Authorities in the Territory with respect to such Licensed Patent or Joint Patent. Abeona shall cooperate with Ultragenyx's reasonable requests in connection therewith.

(c) **Biosimilar Applications**. If either Party receives a copy of an application submitted to the FDA under subsection (k) of Section 351 of the PHSA or any analogous application submitted to any Regulatory Authority in a country outside the United States (a "**Biosimilar Application**") naming a Licensed Product as a reference product or otherwise becomes aware that such a Biosimilar Application has been filed (including by the receipt of information disclosed pursuant to Section 351(l)(2) of the PHSA, or in an instance described in Section 351(l)(9)(C) of the PHSA), such Party will, within [***] Business Days, notify the other Party so that the other Party may seek permission to view the application and related confidential information from the filer of such Biosimilar Application under Section 351(l)(1)(B)(iii) of the PHSA. Ultragenyx will have the first right to (i) designate pursuant to Section 351(l)(1)(B)(ii) of the PHSA the outside counsel and in-house counsel who will receive confidential access to the Biosimilar Application, (ii) (A) list any Licensed Patents, and any other Patents, as required pursuant to Section 351(l)(3)(A), Section 351(l)(5)(b)(i)(II), or Section 351(l)(7) of the PHSA, (B) respond to any communications with respect to such lists from the filer of the Biosimilar Application, and (C) negotiate with the filer of the Biosimilar Application as to whether to utilize a different mechanism for information exchange than that specified in Section 351(l) of the PHSA; and (iii) identify Licensed Patents and any other Patents, and to respond to communications under any equivalent or similar listing in any other jurisdiction in the Territory. If Ultragenyx does not defend a given Patent within the Licensed Patents or Joint Patents under this Section 7.2.4(c) within [***] days (or such shorter period of time before the time limit, if any, set forth in the Applicable Law in the United States or any other country in the Territory to not waive any statutory rights), or elects not to continue any such defense (in which case it will promptly provide notice thereof to Abeona), then Abeona will have the right, but not the obligation, at its sole discretion and expense, to defend any such Patent.

7.3 **Enforcement of Third Party Infringement**.

7.3.1 **Notice**. Each Party will promptly notify the other in writing of any (a) apparent, threatened or actual infringement by a Third Party of any Licensed Patent or Joint Patent, or (b) unauthorized use or misappropriation of any Licensed Know-How by a Third Party of which it becomes aware, and, in each case, will provide the other Party with all evidence in such Party's possession or control supporting such infringement or unauthorized use or misappropriation (each, an "**Infringement**").

7.3.2 **Ultragenyx Sole Right**. As between the Parties, Ultragenyx will have the sole right, but not the obligation, using counsel of its choosing and at its sole expense, to institute any Action alleging Infringement of the Licensed Patents or Joint Patents by a Third Party performing the manufacture, use, marketing or sale of a product falling within the scope of the exclusive license granted to Ultragenyx in Section 2.1 (any such Action, an "**Infringement Action**"). Ultragenyx will notify and keep Abeona reasonably apprised in writing of any such Infringement Action and will consider Abeona's reasonable interests and requests regarding such Infringement Action. If Abeona is joined as a party to any Infringement Action either voluntarily or by an order of the court, Abeona shall have the right to select its own counsel at its sole expense.

7.3.3 **Cooperation**. In any Infringement Action brought under the Licensed Patents or Joint Patents pursuant to Section 7.3.2, Abeona will, and will cause its Affiliates to, reasonably cooperate with Ultragenyx, in good faith, and will join such suit as a party, if requested by Ultragenyx. Furthermore, Ultragenyx will consider in good faith all reasonable and timely comments from Abeona on any proposed arguments asserted or to be asserted in litigation related to the enforcement or defense of any such Patents. Ultragenyx will have the right to settle any patent infringement litigation with respect to any Licensed Patent under this Section 7.3; provided that, if such settlement will diminish the rights or interests of Abeona, then Ultragenyx will consider in good faith reasonable and timely comments from Abeona.

7.3.4 **Expenses**. Subject to Section 7.3.5, Ultragenyx will be solely responsible for all expenses arising from a suit or Action against an Infringement Action, including Abeona's internal expenses (e.g., FTEs) incurred as a result of Abeona's cooperation with the enforcement of an Infringement Action as provided in this Section 7.3. Abeona will be entitled, at Abeona's option, to separate representation in such matter by counsel of its own choice and at its own expense, or by Ultragenyx's counsel at Ultragenyx's expense, but Abeona will at all times cooperate fully with Ultragenyx.

7.3.5 **Allocation of Recoveries**. Any settlements, damages or monetary awards recovered by Ultragenyx pursuant to any Infringement Action with respect to the Licensed Patents or Joint Patents will, after reimbursing the Parties for their reasonable expenses in making such recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses) be retained by Ultragenyx; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) with respect to a Licensed Patent or Joint Patent is attributable to loss of sales or profits with respect to a Licensed Product, such amount will be paid to or retained by Ultragenyx and treated as "Net Sales" in the Calendar Quarter in which the money is actually received and any royalties pursuant to Section 6.3 will be payable by Ultragenyx to Abeona with respect thereto.

7.4 **Defense Against Third Party Infringement Claims**.

7.4.1 **Ultragenyx Right to Control Defense**. Each Party will promptly notify the other Party if a Third Party brings any Action alleging patent infringement by Ultragenyx or Abeona or any of their respective Affiliates or sublicensees with respect to the Exploitation of any Licensed Product (any such Action, an "**Infringement Claim**") in the Territory. Ultragenyx will have the first right, but not the obligation, to control the defense and response to any such Infringement Claim in the Territory, at Ultragenyx's sole cost and expense, and Abeona will have the right, at its own expense, to be represented in any such Infringement Claim in the Territory by counsel of its own choice. Upon the request of Ultragenyx, Abeona will reasonably cooperate with Ultragenyx in the reasonable defense of such Infringement Claim. Abeona will have the right to consult with Ultragenyx concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation. Ultragenyx will (a) consult with Abeona as to the strategy for the prosecution of such defense, (b) consider in good faith any comments from Abeona with respect thereto and (c) keep Abeona reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such defense. Ultragenyx will have the right to settle such Infringement Claim on terms deemed reasonably appropriate by it; provided, that, if such settlement will diminish the rights or interests of Abeona, then Ultragenyx will consider in good faith reasonable and timely comments from Abeona.

7.4.2 **Step-In Right**. If Ultragenyx elects not to defend or control the defense of any Infringement Claim, or otherwise fails to initiate and maintain the defense of any such Infringement Claim, then Abeona may conduct and control the defense of such Infringement Claim at its own expense subject to the terms of Section 7.4.1 (mutatis mutandis, including Abeona in the place of Ultragenyx).

7.5 **Common Interest**. All information exchanged between the Parties regarding the Prosecution of Licensed Patents or Joint Patents under this ARTICLE 7 will be deemed Confidential Information of the disclosing Party. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patents or the Joint Patents under this ARTICLE 7, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this ARTICLE 7 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel's eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

ARTICLE 8
CONFIDENTIALITY AND PUBLICITY

8.1 **Confidential Information**.

8.1.1 **Confidentiality Obligation**. During the Term and for a period of [***] years (and indefinitely with respect to any trade secretes) after any termination or expiration of this Agreement, each Party agrees to, and will cause its Affiliates, its and their sublicensees and subcontractors to, keep in confidence and not to disclose to any Third Party, or use for any purpose, except to exercise its rights or perform its obligations under this Agreement, any Confidential Information of the other Party, without the prior written consent of such disclosing Party. The existence and terms of this Agreement are the Confidential Information of each Party, with each Party treated as the receiving Party.

8.1.2 **Permitted Disclosures**. Each Party agrees that it and its Affiliates will provide or permit access to the other Party's Confidential Information only to the receiving Party's employees, consultants, subcontractors, advisors and sublicensees, and to the employees, consultants, subcontractors, advisors and sublicensees of the receiving Party's Affiliates in each case who need to know to exercise rights or satisfy obligations under this Agreement; provided that such recipients are subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Section 8.1 (but of duration customary in confidentiality agreements entered into for a similar purpose). Each Party will remain responsible for any failure by its Affiliates and its and their sublicensees, and its and its Affiliates' respective employees, consultants, subcontractors and advisors, to treat such Confidential Information as required under this Section 8.1 as if such Affiliates, employees, consultants, subcontractors, advisors and sublicensees were parties directly bound to the requirements of this Section 8.1.

8.1.3 **Confidentiality Limitation**. Notwithstanding anything to the contrary herein, each Party may use and disclose the other Party's Confidential Information as follows: (i) to its Affiliates, *bona fide* potential or actual collaborators, licensors, sublicensees, or strategic partners and to employees, directors, agents, consultants, and advisers of such Third Parties, financial advisors, attorneys and accountants, *bona fide* actual or potential acquisition partners, financing sources or investors and underwriters in all cases on a need to know basis, and under appropriate confidentiality and non-use obligations (which may include professional ethical obligations) no less stringent than those in this Agreement (but of duration customary in confidentiality agreements entered into for a similar purpose); provided, however, that each Party will remain responsible for any failure by any of the foregoing recipients to treat such Confidential Information as required under Section 8.1 as if such recipients were parties directly bound to the requirements of this Section 8.1, (ii) as required by any court governmental body or other Governmental Authority as otherwise required by Applicable Law (including any such disclosures as are required by a Regulatory Authority in connection with seeking Regulatory Approval, Pricing and Reimbursement Approval, import authorization for any Licensed Product in the Territory, or the rules or regulations of the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States or of any stock exchange or listing entity); provided, that, notice is promptly given to the other Party and the receiving Party cooperates with reasonable requests from the other Party to seek a protective order or other appropriate remedy to protect the Confidential Information, or (iii) to a patent authority as may be reasonably necessary or useful for purposes of obtaining Patents as permitted by this Agreement; provided that reasonable measures will be taken to assure confidential treatment of such information, to the extent such protection is available. Notwithstanding anything to the contrary contained in this ARTICLE 8, Confidential Information that is permitted or required to be disclosed will remain otherwise subject to the confidentiality and non-use provisions of Section 8.1.2 and this Section 8.1.3. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar Regulatory Authority in a country other than the United States, then such Party will, within a reasonable time (and in no event less than [***] Business Days) prior to any such filing, provide the other Party with a copy of this Agreement showing any provisions hereof as to which the Party proposes to request confidential treatment and will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions. The Party filing the Agreement will take the other Party's reasonable comments into consideration before filing such agreement and use reasonable efforts to have terms identified by such other Party afforded confidential treatment by the applicable Regulatory Authority.

8.2 **Publicity and Press Release**. The Parties have agreed upon the content of a press release which will be issued jointly by the Parties substantially in the form attached hereto as Schedule 8.2, promptly after the Effective Date. Except for disclosures permitted in accordance with Section 8.1.2 or Section 8.1.3, Abeona will not issue any other public announcement, press release or other public disclosure regarding this Agreement, its subject matter or any amendment hereto without Ultragenyx's prior written consent, except for any such disclosure that repeats any information regarding this Agreement, its subject matter or any amendment hereto that has already been publicly disclosed by either Party in accordance with this Section 8.2; provided that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable. For clarity, Ultragenyx and its Affiliates and its and their Sublicensees will have the right to publicly disclose research, development and commercial information (including with respect to regulatory matters) regarding the Licensed Products; provided such disclosure is subject to the provisions of Section 8.1 with respect to Abeona's Confidential Information.

8.3 **Scientific Publications**.

8.3.1 As between the Parties, Ultragenyx will control all scientific publications relating to all activities undertaken under this Agreement for the relevant Licensed Products, which publications will not require the prior written approval of Abeona. If Ultragenyx or its employees or consultants (such as clinical investigators) wish to publish or publicly present any information about a Licensed Product or the results of any activities relating to the research or development of Licensed Products, which publication contains any of Abeona's Confidential Information, it will deliver to Abeona a copy of the proposed written publication or an outline of an oral disclosure at least [***] days ([***] days in the case of abstracts) prior to submission for publication or presentation. Abeona will respond in writing promptly and in no event later than [***] days ([***] days in the case of abstracts) after receipt of the proposed material and will have the right to propose modifications to the publication or presentation for confidentiality reasons, or request a reasonable delay in publication or presentation in order to protect patentable information that is Controlled by Abeona.

8.3.2 In addition to the foregoing, subject to this Section 8.3, Ultragenyx will have the right at any time during and after the Term to (a) publish the results or summaries of results of all Clinical Studies, observational studies and other studies such a meta analyses, conducted with respect to any and all Licensed Products in any clinical trial register maintained by Ultragenyx or its Affiliates and the protocols of such Clinical Studies on www.clinicaltrials.gov or in each case publish the results, summaries or protocols of such Clinical Studies or other studies on such other websites or repositories or at scientific congresses and in peer-reviewed journals within such timescales as required by Applicable Law or Ultragenyx's or its Affiliate's internal policies and procedures, irrespective of the outcome of such Clinical Studies; and (b) make any other public disclosures of Clinical Data that become required of Ultragenyx due to its internal policies and procedures or Applicable Law.

8.3.3 Each publication made in accordance with this Section 8.3 will not be a breach of the confidentiality provisions set forth in Section 8.1.

8.4 **Equitable Relief**. Given the nature of the Confidential Information and the competitive damage that could result to a Party upon unauthorized disclosure, use or transfer of its Confidential Information to any Third Party, the Parties agree that monetary damages may not be a sufficient remedy for any breach of this ARTICLE 8. In addition to all other remedies, and notwithstanding the provisions of ARTICLE 13, a Party will be entitled to seek specific performance and injunctive and other equitable relief as a remedy for any breach or threatened breach of this ARTICLE 8.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES; CERTAIN COVENANTS

9.1 **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that, as of the Effective Date:

9.1.1 **Organization**. It is a corporation duly organized, validly existing, and in good standing under the Applicable Law of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

9.1.2 **Consents**. Except for any Regulatory Approvals, manufacturing approvals or similar approvals necessary for the Development, Manufacture or Commercialization of Licensed Products, all necessary consents, approvals and authorizations of all Governmental Authorities and other Persons required to be obtained by it in connection with the execution, delivery and performance of this Agreement have been obtained.

9.1.3 **No Conflict**. It is not under any obligation, contractual or otherwise, to any Person that would materially affect the performance of obligations under this Agreement and the execution and delivery of this Agreement by such Party, and the performance of such Party's obligations under this Agreement (as contemplated as of the Effective Date) and the licenses and sublicenses to be granted by such Party pursuant to this Agreement (a) do not conflict with or violate any requirement of Applicable Law applicable to such Party, (b) do not conflict with or violate any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party, and (c) do not conflict with, violate, breach or constitute a default under, or give rise to any right of termination, cancellation or acceleration of, any contractual obligations of such Party or any of its Affiliates.

9.1.4 **Enforceability**. It has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder and this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms, subject to the general principles of equity and subject to bankruptcy, insolvency, moratorium, judicial principles affecting the availability of specific performance and other similar Applicable Law affecting the enforcement of creditors' rights generally.

9.1.5 **Compliance with Applicable Law**. Each Party will comply, and ensure that its Affiliates and its and their sublicensees and subcontractors comply, in all material respects with all Applicable Laws in the performance of its obligations and exercise of its rights under this Agreement to the extent in each case that such Applicable Law cover the performance of the relevant obligations or exercise of rights.

9.1.6 **Authority**. (a) It has the right to grant to the other Party the licenses and sublicenses granted pursuant to this Agreement, (b) it has the right to enter into this Agreement, and (c) the performance by such Party of this Agreement does not violate such Party's charter documents, bylaws or other organizational documents.

9.2 **Additional Representations, Warranties and Covenants of Abeona**. Abeona represents and warrants as of the Effective Date, and covenants to Ultragenyx (as applicable) that:

9.2.1 **Licensed Patents**. Schedule 1.72 sets forth a true, correct and complete list of all Licensed Patents owned by Abeona or any of its Affiliates as of the Effective Date. All Licensed Patents that are owned by Abeona or any of its Affiliates have been Prosecuted in good faith in the patent offices in accordance with Applicable Law. Neither Abeona nor any of its Affiliates holds any exclusive rights to any Patent owned by a Third Party that (i) claim the composition of matter, manufacture or use of any Licensed Product (including use as a monotherapy or in combination with other compositions of matter), or (ii) are necessary for the research, Development, Manufacture, import, export, use, sale or Commercialization of any Licensed Products in the Field in the Territory other than the Licensed Patents.

9.2.2 **Third Party Challenges**. There are no claims, judgments, or settlements against, or amounts with respect thereto, made against Abeona or any of its Affiliates relating to the Licensed Patents or the Upstream Patents or the Licensed Know-How. No claim or litigation has been received by Abeona or its Affiliates or, to Abeona's knowledge, threatened by any Person (i) alleging that any of the Licensed Patents or Upstream Patents is invalid or unenforceable, (ii) challenging Abeona's or its Affiliate's Control of the Licensed Technology (i.e., alleging that a Third Party has a right or interest in or to the Licensed Technology) or (iii) alleging misappropriation of the Know-How of any Third Party used in the Development, Manufacture or Commercialization of Licensed Products by or on behalf of Abeona or any of its Affiliates prior to the Effective Date.

9.2.3 **Non-Infringement of Third Party IP**. To Abeona's knowledge, the Development or Manufacture of Licensed Products, as conducted by Abeona, its Affiliates or its sublicensees, or its subcontractors prior to the Effective Date did not or would not infringe any issued Patent or misappropriate or otherwise violate or misappropriate any Know-How of any Person. No claim of infringement of the Licensed Patents or misappropriation of the Licensed Know-How of any Third Party has been brought or asserted, or to Abeona's knowledge, threatened, against Abeona or any of its Affiliates with respect to the Development, Manufacture or Commercialization of Licensed Products.

9.2.4 **Third Party Infringement**. To Abeona's knowledge, (a) no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate any Licensed Patents, Upstream Patents or Licensed Know-How and (b) there are no activities by Third Parties that would constitute infringement or misappropriation of the Licensed Patents, Upstream Patents or Licensed Know-How.

9.2.5 **Absence of Litigation**. Except as set forth on Schedule 9.2.5, there are no judgments or settlements against or owed by Abeona, its Affiliates or its or their sublicensees, or, to Abeona's knowledge, pending litigation against Abeona, its Affiliates, or its or their sublicensees, or litigation threatened against Abeona, its Affiliates, or its or their sublicensees, in each case related to Licensed Products, including any such litigation relating to any Regulatory Materials that are Controlled by Abeona, its Affiliates or its sublicensees as of the Effective Date. Abeona hereby covenants to Ultragenyx that Abeona will timely pay all amounts due under the Settlement Agreement described in Schedule 9.2.5.

9.2.6 **Inventors**. Each Person who has or has had any ownership rights in or to any Licensed Patents purported to be owned solely by Abeona or any of its Affiliates, has assigned and has executed an agreement assigning its entire right, title, and interest in and to such Licensed Patents to Abeona or its Affiliate, as applicable.

9.2.7 **Accuracy of Data**. All information and data provided by or on behalf of Abeona to Ultragenyx on or before the Effective Date in contemplation of this Agreement was and is true and accurate in all materials respects.

9.2.8 **Employment Practices**. As relevant to this Agreement: (a) neither Abeona nor any of its Affiliates has, and will not, employ child labor, forced labor, or cruel or abusive disciplinary practices in the workplace; (b) neither Abeona nor any of its Affiliates has, and will not, discriminate against any workers on any ground in violation of applicable Law (including race, religion, disability, gender, sexual orientation or gender identity); and (c) Abeona and its Affiliates have paid and will pay each employee at least the minimum wage, provided and will provide each employee with all legally mandated benefits, and has complied and will comply with all applicable Laws on working hours and employment rights in the countries in which it operates.

9.2.9 **Assignment Obligations**. All employees, subcontractors or consultants of Abeona or any of its Affiliates that were involved the Exploitation of any Licensed Product prior to the Effective Date has signed a written obligation to assign to Abeona or its Affiliate, as applicable, all rights in the Patents and Know-How that was conceived, discovered, developed or otherwise made by them in the course of such Exploitation.

9.2.10 **Existing Vendor Agreements**. Abeona has not and, unless so directed by Ultragenyx, will not itself, and will cause its Affiliates not to, amend or modify any of the terms under any of the Existing Vendor Agreements that would in any way have an adverse effect on or otherwise limit or reduce the remedies available to Abeona or any of its Affiliates for breach of contract by the Existing Vendor under such Existing Vendor Agreements, or otherwise adversely affect or diminish Ultragenyx's rights or interests hereunder with respect to the Licensed Products. Other than the Nationwide Children's Agreement, Abeona reasonably believes as of the Effective Date that the Existing Vendor Agreements are all the agreements to which Abeona or any of its Affiliates are a party that are material to the Exploitation of the Licensed Products.

9.2.11 **Nationwide Children's Agreement**.

(a) The Nationwide Children's Agreement is the only agreement pursuant to which Abeona or any of its Affiliates acquired rights to Patents owned by a Third Party that Cover a Licensed Product and all Licensed Know-How is owned solely by Abeona or its Affiliate;

(b) A true, complete and correct copy of the Nationwide Children's Agreement, including all amendments thereto, has been provided or made available to Ultragenyx prior to the Effective Date and Nationwide Children's Agreement is in full force and effect and has not been amended, modified or waived, except as otherwise disclosed to Ultragenyx in writing prior to the Effective Date;

(c) To the knowledge of Abeona, all Patents and Know-How in-licensed by Abeona pursuant to the Nationwide Children's Agreement are free and clear of any liens, charges and encumbrances;

(d) Abeona is current on all financial obligations set forth in the Nationwide Children's Agreement;

(e) Nationwide Children's consented to the assignment of the Nationwide Children's Agreement to Ultragenyx; and

(f) No written notice of breach, default, or termination has been received or given under Nationwide Children's Agreement, and to the knowledge of Abeona, there is no act or omission by Abeona or its Affiliates that would provide a right to terminate such agreement.

9.3 **Anti-Corruption**. The Parties will comply with all applicable Laws concerning bribery, money laundering, or corrupt practices or which in any manner prohibit the giving of anything of value to any official, agent, or employee of any government, political party, or public international organization, candidate for public office, health care professional, or to any officer, director, employee, or representative of any other organization, for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage, or improperly assisting either Party in obtaining or retaining business, specifically including the U.S. Foreign Corrupt Practices Act, and the UK Bribery Act, in each case, in connection with the activities conducted pursuant to this Agreement. Each Party will require all contractors, subcontractors, sublicensees, and other Persons that provide services to it in connection with this Agreement to comply with such Party's obligations under this Section 9.3. For the avoidance of doubt the foregoing prohibited payments include facilitating payments, which are unofficial, improper, small payments or gifts offered or made to a Government Official to secure or expedite a routine or necessary action to which a Party is legally entitled.

9.4 **No Debarment**. Each Party represents and warrants that neither it nor any of its or its Affiliates' employees or agents performing under this Agreement has ever been, or is currently: (a) debarred under 21 U.S.C. § 335a or by any Regulatory Authority; (b) excluded, debarred, suspended, or otherwise ineligible to participate in federal health care programs or in federal procurement or non-procurement programs; (c) listed on the FDA's Disqualified and Restricted Lists for clinical investigators; or (d) convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. Each Party further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents performing under this Agreement is the subject of any investigation or proceeding that could lead to that Party becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, such Party will promptly notify the other Party. Abeona further covenants that if, during the Term of this Agreement, it becomes aware that it or any of its or its Affiliates' employees or agents who were previously involved in the Exploitation of any Licensed Product is the subject of any investigation or proceeding that could lead to that entity becoming a debarred entity or individual, an excluded entity or individual or a convicted entity or individual, Abeona will promptly notify Ultragenyx in writing.

9.5 **No Other Warranties**. EXCEPT AS EXPRESSLY STATED IN THIS ARTICLE 9, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WARRANTIES OF TITLE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY WITH RESPECT TO THE LICENSED PRODUCTS, VALIDITY, ENFORCEABILITY, MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 10
INDEMNIFICATION; DAMAGES

10.1 **Indemnification by Abeona**. Abeona will defend, indemnify and hold harmless Ultragenyx, its Affiliates, Sublicensees and its and their respective directors, officers, employees and agents (each, an "**Ultragenyx Indemnified Party**"), from, against and in respect of any and all Third Party Losses incurred or suffered by any Ultragenyx Indemnified Party to the extent resulting from: (a) any breach of any representation or warranty made by Abeona in this Agreement, or any breach by Abeona or any of its Affiliates, sublicensees, or subcontractors, or any of their respective directors, officers, employees or agents of any obligation, covenant or agreement in this Agreement; (b) the gross negligence or willful misconduct of, or violation of Applicable Law by, Abeona or any of its Affiliates, sublicensees, or subcontractors, or any of their respective directors, officers, employees and agents, in performing Abeona's obligations or exercising Abeona's rights under this Agreement; (c) the Exploitation of the Licensed Products by or for Abeona or any of its Affiliates, its or their sublicensees, subcontractors, agents and consultants or contractors, before the Effective Date or during the Term; (d) use or practice of the Licensed Technology before the Effective Date or during the Term by Abeona or any of its Affiliates, sublicensees, or subcontractors, or any of their respective directors, officers, employees or agents; provided, however, that Abeona's obligations pursuant to this Section 10.1 will not apply to the extent such Third Party Losses result from Third Party Losses for which Ultragenyx has an obligation to indemnify Abeona pursuant to Section 10.2.

10.2 **Indemnification by Ultragenyx**. Ultragenyx will defend, indemnify and hold harmless Abeona, its Affiliates and their respective directors, officers, employees and agents (each, a "**Abeona Indemnified Party**") from, against and in respect of any and all Third Party Losses incurred or suffered by any Abeona Indemnified Party to the extent resulting from: (a) any breach of any representation or warranty made by Ultragenyx in this Agreement, or any breach by an Ultragenyx Indemnified Party of any obligation, covenant or agreement in this Agreement, (b) the gross negligence or willful misconduct of, or violation of Applicable Law by, an Ultragenyx Indemnified Party in performing Ultragenyx's obligations or exercising Ultragenyx's rights under this Agreement, (c) the Exploitation of the Licensed Products by or for an Ultragenyx Indemnified Party; or (d) use or practice of the Licensed Technology by Ultragenyx or any of its Affiliates or Sublicensees; provided, however, that Ultragenyx's obligations pursuant to this Section 10.2 will not apply to the extent such Third Party Losses result from Third Party Losses for which Abeona has an obligation to indemnify Ultragenyx pursuant to Section 10.1.

10.3 **Claims for Indemnification**. Each Party will notify the other Party in writing if it becomes aware of a claim for which such Party may seek indemnification hereunder. If any Action (including any governmental investigation) is instituted against a Party with respect to which indemnity may be sought pursuant to Section 10.1 or Section 10.2, as applicable, such Party (the "**Indemnified Party**") will give prompt written notice of the indemnity claim to the other Party (the "**Indemnifying Party**") and provide the Indemnifying Party with a copy of any complaint, summons or other written notice that the Indemnified Party receives in connection with any such claim. An Indemnified Party's failure to deliver such written notice will relieve the Indemnifying Party of liability to the Indemnified Party under Section 10.1 or Section 10.2, as applicable, only to the extent such delay is prejudicial to the Indemnifying Party's ability to defend such claim. Provided that the Indemnifying Party is not contesting the indemnity obligation, the Indemnified Party will permit the Indemnifying Party to control any litigation relating to such claim and the disposition of such claim by negotiated settlement or otherwise (subject to this Section 10.3) and any failure to contest such obligation prior to assuming control will be deemed to be an admission of the obligation to indemnify. The Indemnifying Party will act reasonably and in good faith with respect to all matters relating to such claim and will not settle or otherwise resolve such claim without the Indemnified Party's prior written consent, unless such settlement or resolution involves only the payment of monetary awards for which the Indemnifying Party will be fully responsible. If the Indemnified Party has a consent right under the foregoing sentence, then such consent will not be unreasonably withheld, conditioned or delayed and it will be reasonable to withhold, condition or delay such consent if such compromise or settlement involves (a) any admission of legal wrongdoing by the Indemnified Party, (b) any payment by the Indemnified Party that is not indemnified under this Agreement, or (c) the imposition of any equitable relief against the Indemnified Party. The Indemnified Party will reasonably cooperate with the Indemnifying Party in the Indemnifying Party's defense of any claim for which indemnity is sought under this Agreement, at the Indemnifying Party's cost and expense.

10.4 **Insurance**. Each Party will maintain, at its cost, insurance or self-insurance with respect to liabilities and other risks associated with its activities and obligations under this Agreement, in such amounts and on such terms as are customary for prudent practices for similarly situated companies in the biotechnology or pharmaceutical industry for the activities to be conducted by such Party under this Agreement. Upon written request, each Party will provide evidence of such insurance to the other Party and ensure that the other Party will receive no less than [***] days' notice of any cancelation, non-renewal or material change in such coverage.

ARTICLE 11
LIMITATION OF LIABILITY

11.1 **No Consequential or Punitive Damages**. EXCEPT AS SET FORTH IN SECTION 11.2, NEITHER PARTY NOR ANY OF ITS AFFILIATES WILL BE LIABLE FOR INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, INCLUDING ANY LOST PROFITS ARISING OUT OF THIS AGREEMENT, IN EACH CASE HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

11.2 **EXCLUSION FROM LIABILITY LIMITATION**. THE LIMITATIONS AND DISCLAIMER SET FORTH IN SECTION 11.1 WILL NOT APPLY TO A CLAIM: (A) FOR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; (B) FOR A BREACH OF ARTICLE 8; OR (C) FOR INDEMNIFIABLE LOSSES PURSUANT TO SECTION 10.1 OR 10.2.

ARTICLE 12
TERM AND TERMINATION

12.1 **Term**. Unless terminated earlier in accordance with this ARTICLE 12, this Agreement will become effective as of the Effective Date and will continue in full force and effect, on a Licensed Product-by-Licensed Product basis, until the end of the Royalty Term for such Licensed Product (the "**Term**").

12.2 **Paid-Up License Upon End of Royalty Term**. Upon the expiration of the Royalty Term for a given Licensed Product, the license granted to Ultragenyx pursuant to Section 2.1 will become perpetual, irrevocable, fully paid-up, and royalty free with respect to such Licensed Product.

12.3 **Early Termination**.

12.3.1 **Termination for Material Breach**. Upon any material breach of this Agreement by a Party (the Party so allegedly breaching being the "**Breaching Party**"), the other Party (the "**Non-Breaching Party**") will have the right, but not the obligation, to terminate this Agreement in its entirety by providing [***] days' written notice to the Breaching Party with respect to any other breach, which notice will, in each case (a) expressly reference this Section 12.3.1, (b) reasonably describe the alleged breach which is the basis of such termination, and (c) clearly state the Non-Breaching Party's intent to terminate this Agreement if the alleged breach is not cured within the [***]-day cure period. The termination will become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period; provided, that if there is a good faith dispute with respect to the existence of a material breach or whether such material breach has been cured, and if such alleged breach or failure to cure is contested in good faith by the Breaching Party in writing within [***] days of the delivery of the breach notice, then the dispute resolution procedure pursuant to ARTICLE 13, may be initiated by either Party to determine whether a material breach or a failure to cure has actually occurred. If either Party so initiates the dispute resolution procedure, then the applicable cure period (and the corresponding termination of this Agreement, in whole or in part), will be tolled as set forth in Section 13.2. Notwithstanding the foregoing, if the breach and failure to cure contemplated by this Section 12.3.1 (i) is with respect to Ultragenyx's breach of its diligence obligations set forth in Sections 4.1 and 4.4 with respect to one or more (but not all) of the countries in the Territory or (ii) relates to some but not all of the Licensed Products, then, in each case ((i) and (ii)), Abeona will not have the right to terminate this Agreement in its entirely, but will have the right to terminate this Agreement solely with respect to the country(ies) or Licensed Product(s) to which such breach and failure to cure applies.

12.3.2 **Termination for Bankruptcy**. This Agreement may be terminated immediately, to the extent permitted by Applicable Law, by either Party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, that in the case of any involuntary bankruptcy, reorganization, liquidation or receivership proceeding such right to terminate will only become effective if the Party subject to such proceeding consents to the involuntary bankruptcy or such proceeding is not dismissed within [***] calendar days after the filing thereof.

12.3.3 **Termination by Ultragenyx for Convenience**. Ultragenyx may terminate this Agreement in its entirety for any or no reason, upon [***] months' prior written notice to Abeona.

12.3.4 **Termination for Safety or Efficacy**. Ultragenyx may terminate this Agreement at any time in its sole discretion upon [***] days' written notice to Abeona in the event Ultragenyx makes a good faith determination in accordance with its standard practices and procedures for such determinations that there is a material safety issue or efficacy concern with respect to the Licensed Products.

12.4 **Effects of Termination**. All of the following effects of termination (but not expiration) are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and will not be construed to limit any such rights or remedies.

12.4.1 **Effects of Termination Generally**. In the event of any termination of this Agreement for any reason:

(a) **Termination of Rights and Obligations**. The Parties' rights, licenses, including any Sublicenses, and obligations under this Agreement will terminate and neither Party will have any further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 12.4.

(b) **Ongoing Clinical Studies**. If at the time of such termination, any Clinical Studies for the Licensed Products are being conducted by or on behalf of Ultragenyx, at Ultragenyx's election, subject to patient safety and well-being, Ultragenyx will, and will cause its Affiliates and Sublicensees to, wind down such Clinical Studies.

(c) **Return of Confidential Information**. Each Party will, and cause its Affiliates to promptly (i) destroy all tangible items solely comprising, bearing or containing any Confidential Information of the other Party that are in such first Party's or its Affiliates' possession or control, and provide written certification of such destruction, or (ii) prepare such tangible items of the other Party's Confidential Information for shipment to such other Party, as such other Party may direct, at the first Party's expense; provided, however, that, in any event, (A) each Party may retain copies of the Confidential Information of the other Party to the extent necessary to perform its obligations or exercise its rights that survive termination of this Agreement; and (B) each Party may retain one copy of the Confidential Information of the other Party for archival and legal compliance purposes in accordance with standard archiving practices.

(d) Notwithstanding the foregoing, if this Agreement is terminated in part with respect to a particular country or Licensed Product, then the effects of termination will be limited to such country or Licensed Product, as applicable.

12.4.2 **Accrued Obligations**. Termination of this Agreement for any reason will not release either Party from any obligation or liability which, on the effective date of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination.

12.4.3 **Survival**. The provisions set forth in the following Sections, as well as, to the extent applicable, any other Sections or defined terms referred to in such Sections or Articles or necessary to give them effect, will survive the expiration or termination of this Agreement in its entirety: ARTICLE 6 (but only with respect to payments accrued thereunder prior to termination), ARTICLE 7 (with respect to the provisions regarding Joint Patents), ARTICLE 8, ARTICLE 10, ARTICLE 11, ARTICLE 13, ARTICLE 14, Sections 2.8, 7.1, 7.5, 12.2, and this Section 12.4. Furthermore, any other provisions required to interpret the Parties' rights and obligations under this Agreement, including applicable definitions in ARTICLE 1, will survive to the extent required.

ARTICLE 13
DISPUTE RESOLUTION

13.1 **Dispute Resolution**. Except as otherwise expressly set forth in this Agreement, disputes of any nature arising under, relating to, or in connection with this Agreement ("**Disputes**") will be resolved pursuant to this ARTICLE 13.

13.2 **Tolling**. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches), as well as all time periods in which a Party must exercise rights or perform obligation hereunder, will be tolled once the Dispute resolution procedures set forth in this ARTICLE 13 have been initiated and for so long as they are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result. Further, with respect to any time periods that have run during the pendency of the Dispute, the applicable Party will have a reasonable period of time or any specific timeframe established by the tribunal's decision to exercise any rights or perform any obligations affected by the running of such time periods.

13.3 **Informal Dispute Resolution; Escalation to Chief Executive Officers**. In the event of any Dispute, the Parties will first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. If, after [***] Business Days from receipt of the written notice of a Dispute, such Dispute has not been resolved on an informal basis, either Party may refer any Dispute to the Chief Executive Officers of the Parties (the "**Executive Officers**") by delivering written notice to the other Party, who will confer in good faith on the resolution of the issue for a [***]-day period following receipt of such written notice. If the Chief Executive Officers are unable to resolve any such Dispute within such [***] day period, then either Party may refer such Dispute for Expedited Arbitration in accordance with Section 13.4.

13.4 **Expedited Arbitration**. Except as otherwise expressly set forth in this Agreement, in the event the Parties have not resolved a Dispute within [***] days of receipt of the written notice referring such Dispute to the Executive Officers, then the Parties will follow the expedited dispute resolution process in this Section 13.4 ("**Expedited Arbitration**"). The Parties agree and acknowledge that any good faith dispute under Expedited Arbitration ("**Expedited Dispute**") will not be deemed to be a material breach of this Agreement. The Expedited Dispute will be submitted to fast-track, binding arbitration in accordance with the following:

13.4.1 Arbitration will be conducted in New York, New York under the Expedited Procedures of the Commercial Arbitration Rules of the American Arbitration Association (the "**AAA**") for the resolution of commercial disputes in the most expedited manner permitted by such rules. The Parties will appoint a single arbitrator to be selected by mutual agreement. If the Parties are unable to agree on an arbitrator, the Parties will request that the AAA select the arbitrator. The arbitrator will be a professional in business or licensing experienced in the valuation of biopharmaceutical products with at least ten (10) years of experience in the pharmaceutical and life sciences industries, including the conduct of research, development and commercialization collaborations. The AAA fees associated with the arbitration will be borne equally by the Parties, and each Party shall bear its own attorneys' fees and costs. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Laws, neither Ultragenyx nor Abeona nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written agreement of Ultragenyx and Abeona.

13.5 **Patent Disputes**. Notwithstanding Section 13.4, any dispute, controversy or claim relating to the inventorship, scope, validity, enforceability or infringement of any Patents Covering the Exploitation of any Licensed Product will be submitted to a court of competent jurisdiction in the country in which such Patents were granted or arose. The sole venue for any dispute regarding a United States patent shall be the United States District Court for the District of Delaware.

13.6 **Injunctive Relief**. Notwithstanding the dispute resolution procedures set forth in this ARTICLE 13, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder or posting any bond.

ARTICLE 14
MISCELLANEOUS

14.1 **Assignment; Successors**.

14.1.1 **Assignment**. This Agreement and the rights and obligations of each Party under this Agreement will not be assignable, delegable, transferable, pledged or otherwise disposed of by either Party without the prior written consent of the other Party; provided, however, that either Party may assign or transfer this Agreement together with all of its rights and obligations hereunder, without such consent (but with written notice to the other Party within [***] days of such assignment or transfer), (A) to an Affiliate or (B) subject to Section 2.6 in the case of Abeona, to a successor in interest in connection with the transfer or sale of all or substantially all of its business or assets to which this Agreement relates, or in the event of its merger or consolidation, reorganization or similar transaction, subject to the assignee agreeing in writing to be bound by the terms and conditions of this Agreement. Any assignment in violation of this Section 14.1.1 will be null and void.

14.1.2 **Successors**. Any permitted assignment of the rights and obligations of a Party under this Agreement will be binding on, and inure to the benefit of and be enforceable by and against, the successors and permitted assigns of the assigning Party. The permitted assignee or transferee will assume all obligations of its assignor or transferor under this Agreement. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.1.2 will be null, void and of no legal effect.

14.2 **Governing Law**. This Agreement will be governed by and interpreted under the laws of the State of New York, without regard to the conflicts of law principles thereof. The Parties agree to exclude the application to this Agreement of the United Nations Conventions on Contracts for the International Sale of Goods (1980).

14.3 **Notices**. All communications hereunder will be in writing or by electronic mail, and will be deemed to have been duly given (a) upon personal delivery, (b) upon deposit with a recognized courier with next-day delivery instructions, or (c) one Business Day after sending, if sent by electronic mail and no delivery failure notification has been received. This Section 14.3 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

If to Abeona:	Abeona Therapeutics Inc. 6555 Carnegie Avenue, 4th Floor Cleveland, OH 44103 Attention: Scott D. Nogi, Head of Business Operations Email: [***] Abeona Therapeutics Inc. 1330 Avenue of the Americas, 33rd Floor New York, NY 10019 Attention: Brendan M. O'Malley, General Counsel Email: [***] and [***]
With copies to:	Cooley LLP 500 Boylston Street 14th Floor Boston, Massachusetts 02116 Attention: Geoffrey Spolyar Email: [***]
If to Ultragenyx:	Ultragenyx Pharmaceutical Inc. 60 Leveroni Court Novato, CA 94949 Attention: Chief Business Officer Email: [***]
With copies to (which will not constitute notice to):	Goodwin Procter LLP 100 Northern Avenue Boston, Massachusetts 02210 Attention: Kathleen Kean Telephone: [***] Email: [***]

14.4 **Severability**. In the event that one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect, then such provision will not render any other provision of this Agreement invalid or unenforceable, and all other provisions will remain in full force and effect and will be enforceable, unless the provisions that have been found to be invalid, illegal or unenforceable will substantially affect the remaining rights or obligations granted or undertaken by either Party. The Parties agree to attempt to substitute for any invalid or unenforceable provision a provision which achieves to the greatest extent possible the objectives of the invalid, illegal or unenforceable provision.

14.5 **Integration**. This Agreement and the Assignment Agreement, together with all schedules and exhibits attached hereto and thereto, constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous arrangements between the Parties with respect to the subject matter hereof, whether written or oral, including, effective as of the Effective Date, the Prior CDA (provided that all information disclosed or exchanged under such agreement will be treated as Confidential Information hereunder). In the event of a conflict between any schedules or attachments to this Agreement, on the one hand, and this Agreement, on the other hand, the terms of this Agreement will govern. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement.

14.6 **Waivers and Amendments**. The failure of any Party to assert a right under this Agreement or to insist upon compliance with any term or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other Party. The exercise by any Party of any right or election under the terms or covenants herein will not preclude or prejudice any Party from exercising the same or any other right it may have under this Agreement, irrespective of any previous action or proceeding taken by the Parties hereunder. Notwithstanding the authority granted to the Joint Transition Team under this Agreement, (a) no waiver will be effective unless it has been given in writing and signed by an authorized representative of the Party giving such waiver, and (b) no provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.

14.7 **Independent Contractors; No Agency**. Neither Party will have any responsibility for the hiring, firing or compensation of the other Party's or such other Party's Affiliates' employees or for any employee benefits with respect thereto. No employee or representative of a Party or its Affiliates will have any authority to bind or obligate the other Party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on such other Party, without such other Party's written approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party's legal relationship under this Agreement to the other Party will be that of independent contractor, and the relationship between the two Parties will not constitute a partnership, joint venture, or agency, including for all tax purposes, except as otherwise required by Applicable Law.

14.8 **Affiliates, Sublicensees, and Subcontractors**. To the extent that this Agreement imposes obligations on Affiliates, Sublicensees or subcontractors of a Party, such Party will cause its Affiliates and its and their sublicensees and subcontractors to perform such obligations, as applicable. Either Party may use one or more of its Affiliates, its or their sublicensees or subcontractors to perform its obligations and duties or exercise its rights under this Agreement, solely to the extent permitted and as specified in this Agreement; provided, however, that (a) each such Affiliate, Sublicensee or subcontractor will perform any such obligations delegated to it in compliance with the applicable terms and conditions of this Agreement as if such Affiliate, Sublicensee or subcontractor were a party hereto, (b) the performance of any obligations of a Party's by its Affiliates, its or their sublicensees or subcontractors will not diminish, reduce or eliminate any obligation of such Party under this Agreement, (c) the Party using such contractor will terminate promptly any subcontractor, and will give the other Party notice of such termination, in the case of any material breach of this Agreement by such subcontractor and (d) subject to such Party's assignment to an Affiliate pursuant to Section 14.1, such Party will remain liable under this Agreement for the prompt payment and performance of all of its obligations under this Agreement. Subject to this Section 14.8, if a Party exercises its rights and performs its obligations under this Agreement through one or more of its Affiliates, "Abeona" will be interpreted to mean "Abeona or its Affiliates" and "Ultragenyx" will be interpreted to mean "Ultragenyx or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to such Party in this Agreement and the ability to perform its obligations under this Agreement.

14.9 **No Third Party Beneficiary Rights**. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they will not be construed as conferring any rights on any other Third Party. This Agreement is not intended to and will not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than, to the extent provided in ARTICLE 10, the Indemnified Parties.

14.10 **Non-exclusive Remedy**. Except as expressly provided herein, the rights and remedies provided herein are cumulative and each Party retains all remedies at law or in equity, including each Party's ability to receive legal damages or equitable relief, with respect to any breach of this Agreement. Neither Party will be required (but, for clarity, will have the right as specified in this Agreement) to terminate this Agreement due to a breach of this Agreement by the other Party.

14.11 **Interpretation**. The Article and Section headings used herein are for reference and convenience only, and will not enter into the interpretation of this Agreement. Except as otherwise explicitly specified to the contrary, (a) references to an Article, Section or Exhibit means an Article or Section of, or a Schedule or Exhibit to this Agreement and all subsections thereof, unless another agreement is specified; (b) references in any Section to any clause are references to such clause of such Section; (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto; (d) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (e) words in the singular or plural form include the plural and singular form, respectively; (f) unless the context requires a different interpretation, the word "or" has the inclusive meaning that is typically associated with the phrase "and/or"; (g) the terms "including," "include(s)," "such as," "e.g." and "for example" mean including the generality of any description preceding such term and will be deemed to be followed by "without limitation"; (h) whenever this Agreement refers to a number of days, such number will refer to calendar days unless Business Days are specified, and if a period of time is specified and dates from a given day or Business Day, or the day or Business Day of an act or event, it is to be calculated exclusive of that day or Business Day; (i) "monthly" means on a calendar month basis, (j) "quarter" or "quarterly" means on a Calendar Quarter basis; (k) "annual" or "annually" means on a Calendar Year basis; (l) "year" means a 365 day period unless Calendar Year is specified; (m) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (n) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (o) a capitalized term not defined herein but reflecting a different part of speech than a capitalized term which is defined herein will be interpreted in a correlative manner; (p) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (q) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits or Schedules); (r) neither Party or its Affiliates will be deemed to be acting "on behalf of" the other Party under this Agreement, except to the extent expressly otherwise provided; (s) provisions that require that a Party, or the Joint Transition Team hereunder "agree", "consent" or "approve" or the like will be deemed to require that such agreement, consent or approval be specific and in writing in a written agreement, letter or approved minutes, but, except as expressly provided herein, excluding instant messaging; and (t) the word "shall" will be construed to have the same meaning and effect as the word "will".

14.12 **Further Assurances**. Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement (including working collaboratively to correct and clerical, typographical, or other similar errors in this Agreement).

14.13 **Ambiguities; No Presumption**. Each of the Parties acknowledges and agrees that this Agreement has been diligently reviewed by and negotiated by and between them, that in such negotiations each of them has been represented by competent counsel and that the final agreement contained herein, including the language whereby it has been expressed, represents the joint efforts of the Parties hereto and their counsel. Accordingly, in interpreting this Agreement or any provision hereof, no presumption will apply against any Party as being responsible for the wording or drafting of this Agreement or any such provision, and ambiguities, if any, in this Agreement will not be construed against any Party under the rule of construction, irrespective of which Party may be deemed to have authored the ambiguous provision.

14.14 **Execution in Counterparts; PDF Signatures**. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed to be an original, and all of which counterparts, taken together, will constitute one and the same instrument even if both Parties have not executed the same counterpart. Signatures provided in Adobe™ Portable Document Format (PDF) sent by electronic mail will be deemed to be original signatures.

14.15 **Export Control**. This Agreement is made subject to any restrictions required by Applicable Law concerning the export of products or technical information from the U.S. or other countries which may be imposed upon or related to the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technology licensed to it or other technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, except in compliance with U.S. export laws and regulations.

[Remainder of this page intentionally blank.]

IN WITNESS WHEREOF, each Party has caused this Agreement to be duly executed by its authorized representative on the Effective Date.

ABEONA THERAPEUTICS INC.

/s/ Vishwas Seshadri

Name: Vishwas Seshadri
Title: President and CEO

ULTRAGENYX PHARMACEUTICAL INC.

/s/ Emil Kakkis

Name: Emil Kakkis
Title: CEO

[Signature Page to License Agreement]

Schedule 1.42

Existing Vendor Agreements

Schedule 1.72

Licensed Patents

Schedule 3.1.2

Transition Plan

Schedule 3.1.4

Transition Costs

Schedule 3.2

Initial Transfer of Licensed Know-How

Schedule 4.1.3

Prior Development Costs

Schedule 8.2

Form of Press Release

Schedule 9.2.5

Absence of Litigation

EXHIBIT 31.1

PRINCIPAL EXECUTIVE OFFICER CERTIFICATION PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vishwas Seshadri, certify that:

1. I have reviewed this report on Form 10-Q of Abeona Therapeutics 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: August 11, 2022

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

PRINCIPAL FINANCIAL OFFICER CERTIFICATION PURSUANT
TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joseph Vazzano, certify that:

1. I have reviewed this report on Form 10-Q of Abeona Therapeutics 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: August 11, 2022

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32

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

In connection with the Quarterly Report of Abeona Therapeutics Inc. (the "Company") on Form 10-Q for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Vishwas Seshadri, President and Chief Executive Officer of the Company, and Joseph Vazzano, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2022

By: */s/ Vishwas Seshadri*
Vishwas Seshadri
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2022

By: */s/ Joseph Vazzano*
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)