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Table of ContentsYâ€‹â€‹UNITED STATESSECURITIES AND EXCHANGE COMMISSIONWASHINGTON, D.C. 20549FORMÂ 10-Q(Mark One)â€‹â€‹â˜’QUARTERLY REPORT PURSUANT TO SECTIONÂ 13 OR 15(d)Â OF THE SECURITIES EXCHANGE ACT OF 1934â€‹â€‹â€‹For the quarterly period ended September 30, 2024â€‹â€‹â€‹ORâ€‹â€‹â˜TRANSITION REPORT PURSUANT TO SECTIONÂ 13 OR 15(d)Â OF THE SECURITIES EXCHANGE ACT OF 1934â€‹For the transition period from ________ to ________Commission File Number: 001-39231PASSAGE BIO,Â INC.(Exact Name of Registrant as Specified in its Charter)â€‹â€‹â€‹Delaware82-2729751(State or other jurisdiction ofincorporation or organization)(I.R.S. EmployerIdentification No.)â€‹â€‹One Commerce Square2005 Market Street, 39th FloorPhiladelphia, PA 19103(Address of principal executive offices)(Zip Code)â€‹Registrantâ€™s telephone number, including area code: (267) 866-0311Securities registered pursuant to SectionÂ 12(b)Â of the Act:â€‹â€‹â€‹â€‹Title of each classTrading Symbol Name of each exchange on which registeredCommon StockPASGThe Nasdaq Stock Market LLC (Nasdaq Global Select Market)â€‹Indicate by check mark whether the registrant (1)Â has filed all reports required to be filed by SectionÂ 13 or 15(d)Â of the Securities Exchange Act of 1934 during the preceding 12Â months (or for such shorter period that the registrant was required to file such reports), and (2)Â has been subject to such filing requirements for the past 90Â days. Yes âŒ§ No â—»Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to RuleÂ 405 of Regulation S-T (Â§232.405 of this chapter) during the preceding 12Â months (or for such shorter period that the registrant was required to submit such files). Yes âŒ§ No â—»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 â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting company,â€ and â€œemerging growth companyâ€ in RuleÂ 12b-2 of the Exchange Act.â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Large accelerated filerÂ Â Â Â â—»Â Â Â Â Accelerated filerÂ Â Â Â â—»Non-accelerated filerâ€‹â˜’â€‹Smaller reporting companyâ€‹â˜’Emerging growth companyâ€‹â˜’â€‹â€‹â€‹â€‹â€‹If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to SectionÂ 13(a)Â of the Exchange Act. â˜Indicate by check mark whether the registrant is a shell company (as defined in RuleÂ 12b-2 of the Exchange Act). Yes â˜ No â˜’â€‹As of November 8, 2024, the registrant had 61,767,286 shares of common stock, $0.0001 par value per share, outstanding.â€‹â€‹â€‹Table of ContentsCAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTSThis Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as â€œaim,â€ â€œmay,â€ â€œwill,â€ â€œshould,â€ â€œexpect,â€ â€œforecast,â€ â€œplan,â€ â€œanticipate,â€ â€œcould,â€ â€œintend,â€ â€œtarget,â€ â€œproject,â€ â€œcontemplate,â€ â€œbelieve,â€ â€œestimate,â€ â€œpredict,â€ â€œpotentialâ€ or â€œcontinueâ€ or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report, including without limitation statements regarding our plans to develop and commercialize our product candidates, the timing and results of our ongoing or planned preclinical studies and clinical trials, risks associated with clinical trials, including our ability to adequately manage clinical activities, unexpected concerns that may arise from additional data or analysis obtained during clinical trials, the timing of and our ability to obtain and maintain regulatory approvals, the clinical utility of our product candidates, our commercialization, marketing and manufacturing capabilities and strategy, our expectations about the willingness of healthcare professionals to use our product candidates, the timing, or amount, of receipt of any potential future milestone and royalty payments, the sufficiency of our cash and cash equivalents, general economic, industry and market conditions, including fluctuating interest rates and inflation, a potential federal government shutdown, instability in the global banking system, and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this Quarterly Report entitled â€œRisk Factorsâ€ and â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ and elsewhere in this Quarterly Report.Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.2Table of ContentsTable of Contentsâ€‹â€‹â€‹â€‹â€‹Â Â Â Â â€‹Page

â€‹â€‹â€‹3Table of ContentsPARTÂ I-FINANCIAL INFORMATIONItemÂ 1. Interim Financial Statements.Passage Bio,Â Inc.Balance Sheetsâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹(Unaudited)â€‹â€‹â€‹(in thousands, except share and per share data)Â Â Â Â SeptemberÂ 30,Â 2024Â Â Â Â DecemberÂ 31,Â 2023AssetsÂ â€‹Â Â Â â€‹Â Â Current assets:Â â€‹Â Â Â â€‹Â Â Cash and cash equivalentsâ€‹$ 32,292â€‹$ 21,709Marketable securitiesâ€‹â€‹ 52,534â€‹â€‹ 92,585Prepaid expenses and other current assetsâ€‹Â 1,210â€‹Â 923Prepaid research and developmentâ€‹Â 1,180â€‹Â 2,742Total current assetsâ€‹Â 87,216â€‹Â 117,959Property and equipment, netâ€‹Â 10,036â€‹Â 15,295Right of use assets - operating leasesâ€‹â€‹ 14,037â€‹Â 16,858Other assetsâ€‹Â 463â€‹Â 433Total assetsâ€‹$

111,752â€‹$ 150,545Liabilities and stockholdersâ€™ equityâ€‹Â â€‹â€‹Â Â Â Current liabilities:â€‹Â â€‹â€‹Â Â Â Accounts payableâ€‹$ 1,489â€‹$ 1,298Accrued expenses and other current liabilitiesâ€‹Â 6,729â€‹Â 11,670Non-refundable sublicense payments receivedâ€‹â€‹ 5,000â€‹â€‹ â€"Operating lease liabilitiesâ€‹â€‹ 3,733â€‹Â 3,373Total current liabilitiesâ€‹Â 16,951â€‹Â 16,341Operating lease liabilities - noncurrentâ€‹Â 22,085â€‹Â 22,921Total liabilitiesâ€‹Â 39,036â€‹Â 39,262â€‹â€‹â€‹â€‹â€‹â€‹â€‹Commitments and contingencies (noteÂ 10)â€‹Â â€‹â€‹Â Â Â â€‹â€‹â€‹â€‹â€‹â€‹Stockholdersâ€™ equity:â€‹Â â€‹â€‹Â Â Â Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding at both SeptemberÂ 30,Â 2024 and DecemberÂ 31,Â 2023â€‹â€‹ â€"â€‹â€‹ â€"Common stock, $0.0001 par value: 300,000,000 shares authorized; 61,767,286 shares issued and outstanding at SeptemberÂ 30,Â 2024 and 54,944,130 shares issued and outstanding at DecemberÂ 31,Â 2023â€‹Â 6â€‹Â 5Additional paidâ€'in capitalâ€‹Â 719,188â€‹Â 705,789Accumulated other comprehensive income (loss)â€‹â€‹ 32â€‹â€‹ (43)Accumulated deficitâ€‹Â (646,510)â€‹Â (594,468)Total stockholdersâ€™ equityâ€‹Â 72,716â€‹Â 111,283Total liabilities and stockholdersâ€™ equityâ€‹$ 111,752â€‹$ 150,545â€‹See accompanying notes to unaudited interim financial statements.â€‹4Table of ContentsPassage Bio,Â Inc.Statements of Operations and Comprehensive Loss(Unaudited)â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Three Months Ended SeptemberÂ 30,Â â€‹Nine Months Ended SeptemberÂ 30,Â (in thousands, except share and per share data)Â Â Â Â 2024Â Â Â Â 2023â€‹2024Â Â Â Â 2023Operating expenses:Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Â Research and developmentâ€‹$ 8,656â€‹$ 15,098â€‹$ 30,621â€‹$ 49,258General and administrativeâ€‹Â 7,251â€‹Â 8,184â€‹Â 20,276â€‹Â 35,295Impairment of long-lived assetsâ€‹â€‹ 4,795â€‹â€‹ 5,390â€‹â€‹ 5,233â€‹â€‹ 5,390Loss from operationsâ€‹Â (20,702)â€‹Â (28,672)â€‹Â (56,130)â€‹Â (89,943)Other income (expense), netâ€‹Â 1,362â€‹Â 1,562â€‹Â 4,088â€‹Â 4,639Net lossâ€‹$ (19,340)â€‹$ (27,110)â€‹$ (52,042)â€‹$ (85,304)Per share information:â€‹Â Â Â Â â€‹Â Â Â Â â€‹Â Â Â Â â€‹Â Â Â Â Net loss per share of common stock, basic and dilutedâ€‹$ (0.31)â€‹$ (0.49)â€‹$ (0.87)â€‹$ (1.56)Weighted average common shares outstanding, basic and dilutedâ€‹Â 61,763,346â€‹Â 54,789,410â€‹Â 59,920,537â€‹Â 54,697,967Comprehensive loss:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Net lossâ€‹$ (19,340)â€‹$ (27,110)â€‹$ (52,042)â€‹$ (85,304)Unrealized gain (loss) on marketable securitiesâ€‹â€‹ 99â€‹â€‹ 148â€‹â€‹ 75â€‹â€‹ 774Comprehensive lossâ€‹$ (19,241)â€‹$ (26,962)â€‹$ (51,967)â€‹$ (84,530)â€‹See accompanying notes to unaudited interim financial statements.â€‹â€‹5Table of ContentsPassage Bio,Â Inc.Statements of Stockholdersâ€™ Equity(Unaudited)â€‹CommonÂ stockâ€‹Additionalâ€‹â€‹AccumulatedÂ otherâ€‹â€‹Accumulatedâ€‹â€‹â€‹(in thousands, except share data)Â Â Â Â SharesÂ Â Â Â AmountÂ Â Â Â paidâ€'inÂ capitalâ€‹â€‹comprehensiveÂ income (loss)â€‹Â Â Â Â deficitâ€‹TotalBalance at July 1, 2024Â 61,754,786â€‹$ 6$ 717,788â€‹$ (67)â€‹$ (627,170)â€‹$ 90,557Exercise of stock options and vesting of restricted stock unitsÂ 12,500â€‹Â â€"Â â€"â€‹Â â€"â€‹Â â€"â€‹Â â€"Unrealized gain (loss) on marketable securitiesÂ â€"â€‹Â â€"Â â€"â€‹Â 99â€‹Â â€"â€‹Â 99Shareâ€'based compensation expenseÂ â€"â€‹Â â€"Â 1,400â€‹Â â€"â€‹Â â€"â€‹Â 1,400Net lossÂ â€"â€‹Â â€"Â â€"â€‹Â â€"â€‹Â (19,340)â€‹Â (19,340)Balance at SeptemberÂ 30,Â 2024Â 61,767,286â€‹$ 6$ 719,188â€‹$ 32â€‹$ (646,510)â€‹$ 72,716â€‹CommonÂ stockâ€‹Additionalâ€‹â€‹AccumulatedÂ otherâ€‹â€‹Accumula thousands, except share data)Â Â Â Â SharesÂ Â Â Â AmountÂ Â Â Â paidâ€'inÂ capitalâ€‹â€‹comprehensiveÂ income (loss)â€‹Â Â Â Â deficitâ€‹TotalBalance at January 1, 2024Â 54,944,130â€‹$ 5$ 705,789â€‹$ (43)â€‹$ (594,468)â€‹$ 111,283Issuance of common stock under the ATM Facility, net of offering costsâ€‹ 6,000,000â€‹â€‹ 1â€‹ 8,741â€‹â€‹ â€"â€‹â€‹ â€"â€‹ 8,742Exercise of stock options and vesting of restricted stock unitsÂ 724,591â€‹Â â€"Â 35â€‹Â â€"â€‹Â â€"â€‹Â 35Issuance of shares in connection with employee stock purchase planâ€‹ 98,565â€‹â€‹ â€"â€‹ 50â€‹â€‹ â€"â€‹â€‹ â€"â€‹â€‹ 50Unrealized gain (loss) on marketable securitiesÂ â€"â€‹Â â€"Â â€"â€‹Â 75â€‹Â â€"â€‹Â 75Shareâ€'based compensation expenseÂ â€"â€‹Â â€"Â 4,573â€‹Â â€"â€‹Â â€"â€‹Â 4,573Net lossÂ â€"â€‹Â â€"Â â€"â€‹Â â€"â€‹Â (52,042)â€‹Â (52,042)Balance at SeptemberÂ 30,Â 2024Â 61,767,286â€‹$ 6$ 719,188â€‹$ 32â€‹$ (646,510)â€‹$ 72,716â€‹â€‹â€‹See accompanying notes to unaudited interim financial statements.â€‹â€‹6Table of ContentsPassage Bio,Â Inc.Statements of Stockholdersâ€™ Equity(Unaudited)â€‹Common stockâ€‹Additionalâ€‹â€‹AccumulatedÂ otherâ€‹â€‹Accumulatedâ€‹â€‹â€‹(in thousands, except share data)â€‹Sharesâ€‹Amountâ€‹paidâ€'inÂ capitalâ€‹â€‹comprehensiveÂ income (loss)â€‹Â Â Â Â deficitâ€‹TotalBalance at July 1, 2023Â Â Â Â 54,745,680â€‹$ 5$ 701,349â€‹$ (340)â€‹$ (550,600)â€‹$ 150,414Exercise of stock options and vesting of restricted stock unitsÂ 67,292â€‹â€‹ â€"â€‹ â€"Â â€"â€‹â€‹ â€"â€‹â€‹ â€"Unrealized gain (loss) on marketable securitiesÂ â€"â€‹â€‹ â€"Â â€"â€‹â€‹ 148â€‹â€‹ â€"â€‹â€‹ 148Shareâ€'based compensation expenseÂ â€"â€‹â€‹ â€"â€‹ 2,824â€‹â€‹ â€"â€‹â€‹ â€"â€‹â€‹ 2,824Net lossÂ â€"â€‹â€‹ â€"â€‹ â€"â€‹â€‹ â€"â€‹â€‹ (27,110)â€‹â€‹ (27,110)Balance at SeptemberÂ 30,Â 2023â€‹ 54,812,972â€‹$ 5$ 704,173â€‹$ (192)â€‹$ (577,710)â€‹$ 126,276â€‹Common stockâ€‹Additionalâ€‹â€‹AccumulatedÂ otherâ€‹â€‹Accumulatedâ€‹â€‹â€‹(in thousands, except share data)Â Â Â Â Sharesâ€‹Amountâ€‹paidâ€'inÂ capitalâ€‹â€‹comprehensiveÂ income (loss)â€‹Â Â Â Â deficitâ€‹TotalBalance at January 1, 2023Â 54,614,690â€‹$ 5$ 694,733â€‹$ (966)â€‹$ (492,406)â€‹$ 201,366Exercise of stock options and vesting of restricted stock unitsâ€‹ 98,042â€‹â€‹ â€"â€‹ â€"â€‹â€‹ â€"â€‹â€‹ â€"â€‹â€‹ â€"Issuance of shares in connection with employee stock purchase planâ€‹ 100,240â€‹â€‹ â€"â€‹ 89â€‹â€‹ â€"â€‹â€‹ â€"â€‹â€‹ 89Unrealized gain (loss) on marketable securitiesâ€‹ â€"â€‹â€‹ â€"Â â€"â€‹â€‹ 774â€‹â€‹ â€"â€‹â€‹ 774Shareâ€'based compensation expenseÂ â€"â€‹â€‹ â€"â€‹ 9,351â€‹â€‹ â€"â€‹â€‹ â€"â€‹â€‹ 9,351Net lossÂ â€"â€‹â€‹ â€"â€‹ â€"â€‹â€‹ â€"â€‹â€‹ (85,304)â€‹â€‹ (85,304)Balance at SeptemberÂ 30,Â 2023Â 54,812,972â€‹$ 5$ 704,173â€‹$ (192)â€‹$ (577,710)â€‹$ 126,276â€‹See accompanying notes to unaudited interim financial statements.â€‹â€‹7Table of ContentsPassage Bio,Â Inc.Statements of Cash Flows(Unaudited)â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Nine Months Ended â€‹â€‹SeptemberÂ 30,Â (in thousands)Â Â Â Â 2024Â Â Â Â 2023Cash flows used in operating activities:Â â€‹Â Â Â â€‹Â Â Net lossâ€‹$ (52,042)â€‹$ (85,304)Adjustments to reconcile net loss to net cash provided by (used in) operating activities:â€‹Â â€‹â€‹Â Â Â Depreciation and amortizationâ€‹Â 2,362â€‹Â 2,914Shareâ€'based compensationâ€‹Â 4,573â€‹Â 9,351Amortization of premium and discount on marketable securities, netâ€‹â€‹ (1,162)â€‹â€‹ (1,188)Loss on disposal of property and equipmentâ€‹Â â€"â€‹Â 463Impairment of long-lived assetsâ€‹â€‹ 5,233â€‹Â 5,390Changes in operating assets and liabilities:â€‹Â Â Â â€‹Â Â Â â€‹Prepaid expenses and other current assets, and other assetsâ€‹Â (117)â€‹Â 3,478Prepaid research and developmentâ€‹Â 1,562â€‹Â 4,859Non-refundable sublicense payments receivedâ€‹â€‹ 5,000â€‹â€‹ â€"Right of use assets and operating lease liabilities â€‹(171)â€‹â€‹ (97)Accounts payableâ€‹Â 191â€‹Â (1,316)Accrued expenses and other current liabilitiesâ€‹Â (4,941)â€‹Â 2,702Net cash provided by (used in) operating activitiesâ€‹Â (39,512)â€‹Â (58,748)Cash flows provided by (used in) investing activities:â€‹Â Â Â â€‹Â Â Â Purchases of marketable securitiesâ€‹Â (72,594)â€‹Â (101,640)Sales or maturities of marketable securitiesâ€‹Â 113,882â€‹Â 159,410Purchases of property and equipmentâ€‹Â (20)â€‹Â (133)Net cash provided by (used in) investing activitiesâ€‹Â 41,268â€‹Â 57,637Cash flows provided by (used in) financing activities:â€‹Â Â Â â€‹Â Â Â Proceeds from issuance of common stock under the ATM Facility, net of offering costsâ€‹ 8,742â€‹â€‹ â€"Proceeds from the exercise of stock optionsâ€‹Â 35â€‹Â â€"Proceeds from the issuance of common stock under employee stock purchase planâ€‹â€‹ 50â€‹â€‹ 89Net cash provided by (used in) financing activitiesâ€‹Â 8,827â€‹Â 89Net increase (decrease) in cash and cash equivalentsâ€‹Â 10,583â€‹Â (1,022)Cash and cash equivalents at beginning of periodâ€‹Â 21,709â€‹Â 34,601Cash and cash equivalents at end of periodâ€‹$ 32,292â€‹$ 33,579Supplemental disclosure of nonâ€'cash investing and financing activities:â€‹Â Â Â â€‹Â Â Â Unrealized gain (loss) on marketable securitiesâ€‹$ 75â€‹$ 774Right of use assets recognized upon the commencement of subleaseâ€‹$ (422)â€‹$ â€"Operating lease liabilities recognized upon the commencement of subleaseâ€‹$ 422â€‹$ â€"â€‹See accompanying notes to unaudited interim financial statements.â€‹8Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statements1. Nature of OperationsPassage Bio, Inc., or the Company, a Delaware corporation incorporated in July 2017, is a clinical stage genetic medicines company on a mission to improve the lives of patients with neurodegenerative diseases. The Companyâ€™s primary focus is the development and advancement of cutting-edge, one-time therapies designed to target critical underlying pathology in these conditions. The Company has a strategic research collaboration with the Trustees of the University of Pennsylvaniaâ€™s, or Penn, Gene Therapy Program, or GTP. Through this collaboration, the Company has developed its lead clinical product candidate, PBFT02, for the treatment of frontotemporal dementia, or FTD, caused by progranulin deficiency, or FTD-GRN, which seeks to elevate progranulin levels to restore lysosomal function and slow disease progression. On July 31, 2024, the Company entered into a series of agreements in connection with the planned transition of GTP to two new genetic medicines companies co-founded by Dr. James Wilson: GEMMA Biotherapeutics, or Gemma, and Franklin Biolabs. As a result, the Company established a new research, collaboration and license agreement with Gemma and amended its research collaboration with Penn.2. Risks and LiquidityThe Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of $646.5 million as of SeptemberÂ 30,Â 2024. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates currently in development. Substantial additional capital will be needed by the Company to fund its operations and to develop its product candidates.The Companyâ€™s operations have consisted primarily of conducting preclinical studies, developing licensed technology, conducting clinical trials, and the development and manufacturing of clinical supply to support clinical trials. The Company faces risks associated with early-stage biotechnology companies whose product candidates are in development. Product candidates currently under development will require significant additional research and development efforts and establishing manufacturing capacity and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital for the Company to complete its research and development, achieve its research and development objectives, defend its intellectual property rights, and recruit and retain skilled personnel, and key members of management. Even if the Companyâ€™s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.On March 5, 2021, the Company entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, relating to the applicable terms of at-the-market equity offerings, or the ATM Facility, pursuant to which the Company may, but is not obligated to, offer and sell, from time to time, shares of its common stock with an aggregate offering price up to $125.0 million through Cowen, as sales agent in the ATM Facility. The Company issued 6,000,000 shares of common stock under the ATM Facility, resulting in net proceeds of $8.7 million, after deducting offering costs of $0.3 million in March 2024. The Company is limited to $50.0 million in its capacity to offer and sell shares of its common stock under this sales agreement pursuant to its shelf registration statement on Form S-3, filed on March 4, 2024. As of SeptemberÂ 30,Â 2024, $50.0 million of capacity remains available to be sold under the ATM Facility.The Company plans to seek additional funding through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Companyâ€™s stockholders. If the Company is unable to obtain funding or prospects of funding are unfavorable, the Company could be required to further delay, reduce or eliminate research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects.9Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsIn accordance with Accounting Standards Update, or ASU, No. 2014-15, Disclosure of Uncertainties about an Entityâ€™s Ability to Continue as a Going Concern, the Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Companyâ€™s ability to continue as a going concern within one year after the date that the financial statements are issued. As of the issuance date of these financial statements, the Company expects that its cash, cash equivalents and marketable debt securities will be sufficient to fund its forecasted operating expenses and capital expenditure requirements for at least the next 12 months from the issuance date of these financial statements.3.Â Summary of Significant Accounting PoliciesThe Companyâ€™s complete summary of significant accounting policies can be found in â€œNote 3. Summary of Significant Accounting Policiesâ€ in the audited financial statements included in the Companyâ€™s Annual Report filed on Form 10-K for the year ended DecemberÂ 31,Â 2023.Basis of PresentationThe accompanying unaudited financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Updates promulgated by the Financial Accounting Standards Board, or FASB.Interim Financial StatementsThe accompanying unaudited interim financial statements have been prepared from the books and records of the Company in accordance with GAAP for interim financial information and RuleÂ 10-01 of RegulationÂ S-X promulgated by the SEC, which permits reduced disclosures for interim periods. All adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the accompanying balance sheets, statements of operations and comprehensive loss, stockholdersâ€™ equity, and cash flows have been made. Although these interim financial statements do not include all of the information and footnotes required for complete annual financial statements, management believes the disclosures are adequate to make the information presented not misleading. Unaudited interim results of operations and cash flows are not necessarily indicative of the results that may be expected for the fullÂ year. Unaudited interim financial statements and footnotes should be read in conjunction with the audited financial statements and footnotes included in the Companyâ€™s 2023 Annual Report filed on Form 10-K.Use of EstimatesThe preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.Estimates and assumptions are periodically reviewed, and the effects of the revisions are reflected in the accompanying financial statements in the period they are determined to be necessary. Fair Value of Financial InstrumentsManagement believes that the carrying amounts of the Companyâ€™s financial instruments, including cash equivalents, prepaid expenses, and accounts payable, approximate fair value due to the short-term nature of those instruments. 10Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsConcentration of Credit RiskFinancial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company maintains a deposit account in a federally insured financial institution in excess of federally insured limits. The Company also maintains a money market account in a federally insured financial institution in excess of federally insured limits. The Company has not experienced any losses in such accounts and believes it is not exposed to significant risk on its cash and cash equivalents beyond the normal credit risk associated with commercial banking relationships.The Company maintains a portfolio of marketable debt securities, which is diversified to limit exposure related to counterparty risk, industry risk, and security type risk. The Company maintains an investment policy which dictates the allocation of funds within its portfolio of marketable debt securities. The Company has not experienced any material losses in such portfolio.Segment InformationOperating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one segment.Cash and Cash EquivalentsThe Company considers all highly-liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents as of SeptemberÂ 30,Â 2024 consisted of various securities as described in Note 4. Cash consists of cash deposits at banking institutions.Marketable SecuritiesThe Company classifies its marketable securities with original maturities of greater than three months as available-for-sale. Marketable securities as of SeptemberÂ 30,Â 2024, consisted of various securities as described in Note 4. These securities are carried at fair market value, with unrealized gains and losses reported in comprehensive loss and accumulated other comprehensive income (loss) within stockholdersâ€™ equity. Any premium or discount arising at purchase of debt securities is amortized and/or accreted over the term of the security to other income (expense), net. Gains or losses on marketable securities sold are recognized as a component of other income (expense), net in the statement of operations and comprehensive loss on the specific identification method. All marketable securities are available for use, as needed, to fund operations and therefore, the Company classifies all marketable securities as current assets within the balance sheet.Property and Equipment, NetProperty and equipment, net consists of laboratory equipment, office equipment, computer hardware and software, furniture and fixtures, and leasehold improvements and is recorded at cost. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed as incurred. Property and equipment are depreciated on a straight-line basis over their estimated useful lives. The Company estimates useful life on an asset-by-asset basis, which generally consists of three years for computer hardware and software, five years for office equipment, five years for laboratory equipment, and seven years for furniture and fixtures. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset.When property and equipment are retired or otherwise disposed of, the costs and accumulated depreciation are removed from the respective accounts, with any resulting gain or loss recognized concurrently. The Company did not recognize any losses on disposals of property and equipment for the three and nine months ended SeptemberÂ 30,Â 2024. The 11Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsCompany recognized losses on disposals of property and equipment of $0 and $0.5 million within research and development expenses for the three and nine months ended SeptemberÂ 30,Â 2023, respectively.The Company reviews long-lived assets, such as property and equipment, for impairment

when events or changes in circumstances indicate the carrying amount of the assets may not be recoverable. The Company recognized impairment expenses for property and equipment of $2.3 million and $2.7 million for the three and nine months ended SeptemberÂ 30,Â 2024, respectively. The Company recognized impairment expenses for property and equipment of $3.2 million for the three and nine months ended SeptemberÂ 30,Â 2023. These impairment expenses primarily relate to the proportional allocation of total impairments recognized for the asset groups subject to impairment testing as further described in Note 9.LeasingThe Company evaluates leases at their inception to determine if they are an operating lease or a finance lease. As of SeptemberÂ 30,Â 2024, the Company has classified all leases with terms greater than one year, as operating leases. The Company recognizes assets and liabilities for operating leases at their inception, based on the present value of all payments due under the lease agreement. The Company uses its incremental borrowing rate to determine the present value of operating leases, which is determined by referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. The Company utilizes the accounting policy election to not separate lease and non-lease components and the accounting policy election to not apply the recognition requirement to leases with a term of 12 months or less.The Company reviews long-lived assets, such as right of use assets, or ROU assets, for impairment when events or changes indicate the carrying amount of the ROU assets may not be recoverable. The Company recognized impairment expenses for ROU assets of $2.5 million for the three and nine months ended SeptemberÂ 30,Â 2024. The Company recognized impairment expenses for ROU assets of $2.2 million for the three and nine months ended SeptemberÂ 30,Â 2023. These impairment expenses include the proportional allocation of total impairments recognized for the asset groups subject to impairment testing as further described in Note 9.Share-Based CompensationThe Company measures share-based awards at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards. The Companyâ€™s share-based compensation consists of restricted stock units, or RSUs, and options to purchase common stock, or stock option awards.The Company uses the Black-Scholes option pricing model to value its stock option awards.Estimating the fair value of stock option awards requires the input of assumptions, including, the expected term of stock options, and stock price volatility. The assumptions used in estimating the fair value of share-based awards represent managementâ€™s estimate and involve inherent uncertainties and the application of managementâ€™s judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different for future awards. The expected term of the stock options is estimated using the â€œsimplified method,â€ as the Company has limited historical information from which to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock option grants. The simplified method is the midpoint between the vesting period and the contractual term of the option. For stock price volatility, the Company uses a composite of comparable public company data as a basis for its expected volatility to calculate the fair value of option grants. The selection of comparable public company data requires the application of managementâ€™s judgement.12Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsThe Company accounts for forfeitures of RSUs and stock option awards as they occur.License and Other Revenue The Company may enter into license agreements and transition services agreements (see Note 8) under which it may license rights to research, develop, manufacture, and commercialize its product candidates to third parties, and provide transition services for such licenses. Payments under these arrangements may include non-refundable, upfront fees, reimbursement of certain costs, payments upon the achievement of certain milestones, and royalties on product sales. The Company applies ASC Topic 606,â€¯Revenue from Contracts with Customers, or ASCâ€¯606, when all of the following criteria are met, to determine a valid contract exists: (i) the parties have approved the contract and are committed to perform their respective obligations; (ii) the Company can identify each partyâ€™s rights regarding the goods or services to be transferred; (iii) the Company can identify the payment terms for the goods or services to be transferred; (iv) the contract has commercial substance; and (v) the Company will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. Once it is determined that a valid contract exists, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including consideration of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations on a relative stand-alone selling price basis; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must use its judgment to determine the number of performance obligations, the transaction price, the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price, the contract term and pattern of satisfaction of the performance obligations. The Company uses judgment to determine whether milestones or other variable consideration, except for certain sales-based milestone payments and royalties, should be included in the transaction price as described further below.At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method set forth in ASC 606. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as those subject to regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the statements of operations in the period of adjustment.For customer contracts in the scope of ASC 606, amounts due to the Company are recorded as accounts receivable on the Companyâ€™s balance sheet when the Companyâ€™s right to consideration is unconditional. Amounts received prior to satisfying the related performance obligations are classified on the Companyâ€™s balance sheet as current deferred revenue if expected to be recognized as revenue within 12 months following the balance sheet date and as deferred revenue, net of current portion, if amounts are not expected to be recognized as revenue within the 12 months following the balance sheet date. The Company does not evaluate a contract for a significant financing component if payment is expected within one year or less from the transfer of promised items to the customer.Research and DevelopmentResearch and development costs are expensed as incurred and consist primarily of expenses incurred with GTP, Gemma, contract research organizations, contract manufacturing organizations, internal analytical and testing activities, and 13Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementsemployee-related expenses, including salaries, benefits, and share-based compensation. Management makes estimates of the Companyâ€™s external accrued research and development expenses, which primarily relates to contract research organizations and contract manufacturing organizations, as of each balance sheet date in the Companyâ€™s financial statements based on an estimate of progress to completion of specific tasks using facts and circumstances known to the Company at that time. The Company determines the estimates by reviewing contracts, vendor agreements, change orders, and through discussions with the Companyâ€™s internal clinical personnel and external service providers as to the progress to completion of services and the agreed-upon fee to be paid for such services. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual and related expenses accordingly. Other Income (Expense), NetOther income (expense), net consists of interest earned on cash equivalents and marketable securities, amortization of premium and discount on marketable securities, and income from subleases. Additionally, in the nine months ended SeptemberÂ 30,Â 2023, the Company recognized other income related to the sale of certain tax credits.The Company recorded $1.4 million to other income (expense), net for the three months ended SeptemberÂ 30,Â 2024, which consisted of $1.1 million attributable to interest income and the amortization of premium and discount on the Companyâ€™s marketable securities, and $0.3 million related to income from subleases. The Company recorded $1.6 million to other income (expense), net for the three months ended SeptemberÂ 30,Â 2023, which consisted of $1.6 million attributable to interest income and the amortization of premium and discount on the Companyâ€™s marketable securities.The Company recorded $4.1 million to other income (expense), net for the nine months ended SeptemberÂ 30,Â 2024, which consisted of $3.5 million attributable to interest income and the amortization of premium and discount on the Companyâ€™s marketable securities, and $0.6 million related to income from subleases. The Company recorded $4.6 million to other income (expense), net for the nine months ended SeptemberÂ 30,Â 2023, which consisted of $4.1 million attributable to interest income and the amortization of premium and discount on the Companyâ€™s marketable securities, and $0.5 million related to the sale of certain tax credits.Net Loss Per ShareBasic net loss per share of common stock is computed by dividing net loss by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as stock options, which would result in the issuance of incremental shares of common stock. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive.The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of common stock outstanding, as they would be anti-dilutive:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Nine Months Ended SeptemberÂ 30,Â â€‹2024Â Â Â 2023Stock optionsâ€‹ 12,012,051Â 10,240,051Unvested restricted stock unitsâ€‹ 330,167â€‹ 1,146,499Employee stock purchase planâ€‹ 104,404â€‹ 118,059â€‹â€‹ 12,446,622Â 11,504,609â€‹14Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsRecently Issued Accounting PronouncementsIn November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which expands segment disclosures by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segmentâ€™s profit or loss and assets. The disclosures required under ASU 2023-07 are also required for public entities with a single reportable segment. ASU 2023-07 is effective for the Companyâ€™s first fiscal year beginning after December 15, 2023 and for interim periods within the Companyâ€™s first fiscal year beginning after December 15, 2024, with early adoption permitted. The Company does not expect the adoption of ASU 2023-07 to have a material impact on its financial statements or disclosures. In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, or ASU 2023-09, which requires that an entity, on an annual basis, disclose additional income tax information, primarily related to the rate reconciliation and income taxes paid. The amendments in ASU 2023-09 are intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in this ASU are effective for annual periods beginning after December 15, 2024 with early adoption permitted. The Company is currently evaluating the impact of this guidance on its disclosures.In November 2024, the FASB issued ASU No. 2024-03, Income Statement â€“ Reporting Comprehensive Income â€“ Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses, or ASU 2024-03, which requires entities to provide disclosures to disaggregate operating expenses into specific categories, such as salaries and wages, depreciation, and amortization, to provide enhanced transparency into the nature and function of expenses. ASU 2024-03 is effective for the Companyâ€™s first fiscal year beginning after December 15, 2026, and for interim periods within the Companyâ€™s first fiscal year beginning after December 15, 2027, with early adoption permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the impact of this guidance on its disclosures.4.Â Cash, Cash Equivalents and Marketable SecuritiesThe following table provides details regarding the Companyâ€™s portfolio of cash and cash equivalents:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Cost orâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹(in thousands)Â Â Â Amortized costÂ Â Â Unrealized gainsÂ Â Â Unrealized lossesÂ Â Â Fair valueSeptemberÂ 30,Â 2024:Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Cash accounts in banking institutionsâ€‹$ 3,952â€‹$ -â€‹$ -â€‹$ 3,952Money market fundsâ€‹â€‹ 19,689â€‹â€‹ -â€‹â€‹ -â€‹â€‹ 19,689Commercial paperâ€‹â€‹ 7,594â€‹â€‹ -â€‹â€‹ -â€‹â€‹ 7,594Certificates of depositâ€‹â€‹ 1,057â€‹â€‹ -â€‹â€‹ -â€‹â€‹ 1,057Totalâ€‹$ 32,292â€‹$ -â€‹$ -â€‹$ 32,292â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹DecemberÂ 31,Â 2023:â€‹Â Â Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Cash accounts in banking institutionsâ€‹$ 3,596â€‹$ -â€‹$ -â€‹$ 3,596Money market fundsâ€‹â€‹ 13,763â€‹â€‹ -â€‹â€‹ -â€‹â€‹ 13,763Commercial paperâ€‹â€‹ 2,670â€‹â€‹ -â€‹â€‹ -â€‹â€‹ 2,670Corporate debt securitiesâ€‹â€‹ 1,680â€‹â€‹ -â€‹â€‹ -â€‹â€‹ 1,680Totalâ€‹$ 21,709â€‹$ -â€‹$ -â€‹$ 21,709â€‹15Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsThe following table provides details regarding the Companyâ€™s portfolio of marketable securities:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹(in thousands)Â Â Â Amortized costÂ Â Â Unrealized gainsÂ Â Â Unrealized lossesÂ Â Â Fair valueSeptemberÂ 30,Â 2024:Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Certificates of depositâ€‹$ 5,889â€‹$ 5â€‹$ (1)â€‹$ 5,893Commercial paperâ€‹â€‹ 35,943â€‹â€‹ 30â€‹â€‹ -â€‹â€‹ 35,973Corporate debt securitiesâ€‹â€‹ 3,366â€‹â€‹ 4â€‹â€‹ -â€‹â€‹ 3,370U.S. government securitiesâ€‹â€‹ 7,304â€‹â€‹ -â€‹â€‹ (6)â€‹â€‹ 7,298Totalâ€‹$ 52,502â€‹$ 39â€‹$ (7)â€‹$ 52,534â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹DecemberÂ 31,Â 2023:Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Â â€‹Â Â Certificates of depositâ€‹$ 10,950â€‹$ 6â€‹$ -â€‹$ 10,956Commercial paperâ€‹â€‹ 34,601â€‹â€‹ 9â€‹â€‹ (4)â€‹â€‹ 34,606Corporate debt securitiesâ€‹â€‹ 22,940â€‹â€‹ 8â€‹â€‹ (8)â€‹â€‹ 22,940U.S. government securitiesâ€‹â€‹ 16,049â€‹â€‹ 0â€‹â€‹ (44)â€‹â€‹ 16,005U.S. government agency securitiesâ€‹â€‹ 8,088â€‹â€‹ -â€‹â€‹ (10)â€‹â€‹ 8,078Totalâ€‹$ 92,628â€‹$ 23â€‹$ (66)â€‹$ 92,585â€‹â€‹The contractual maturities of the Companyâ€™s marketable securities as of SeptemberÂ 30,Â 2024, are as follows:â€‹â€‹â€‹â€‹â€‹â€‹(in thousands)â€‹Amortized Costâ€‹Fair ValueDue within one yearâ€‹$ 52,502â€‹$ 52,534Due after one year through five yearsâ€‹â€‹ -â€‹â€‹ -Totalâ€‹$ 52,502â€‹$ 52,534â€‹â€‹5.Â Fair Value of Financial Instruments and Non-Financial Instruments Financial InstrumentsFair value is the price that could be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value determination in accordance with applicable accounting guidance requires that a number of significant judgments be made. Additionally, fair value is used on a nonrecurring basis to evaluate assets for impairment or as required for disclosure purposes by applicable accounting guidance on disclosures about fair value of financial instruments. Depending on the nature of the assets and liabilities, various valuation techniques and assumptions are used when estimating fair value. The carrying amounts of certain of the Companyâ€™s financial instruments, including prepaid expense and accounts payable are shown at cost, which approximates fair value due to the short-term nature of these instruments. The Company follows the provisions of ASC Topic 820, Fair Value Measurement, for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements be classified and disclosed in one of the following three categories:â—LevelÂ 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.â—LevelÂ 2: Quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liabilities.â—LevelÂ 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e.,Â supported by little or no market activity).16Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsThe following fair value hierarchy table presents information about the Companyâ€™s assets measured at fair value on a recurring basis. Included within cash and cash equivalents on the balance sheet, but excluded from the fair value hierarchy table, are cash deposits held at financial institutions:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Fair value measurement atâ€‹â€‹reporting date usingâ€‹â€‹Quoted pricesâ€‹â€‹â€‹â€‹â€‹â€‹â€‹Â in activeÂ SignificantÂ â€‹â€‹â€‹Â â€‹markets
forÂ otherÂ Significantâ€‹Â identicalÂ observableÂ â€‹unobservableâ€‹Â assetsÂ inputsâ€‹inputs(in
thousands)Â Â Â (LevelÂ 1)Â Â Â (LevelÂ 2)Â Â Â (LevelÂ 3)SeptemberÂ 30,Â 2024:Â â€‹Â Â Â â€‹Â Â Â AssetsÂ â€‹Â Â Â â€‹Â Â Â â€‹Â Â Cash equivalents:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Money market fundsâ€‹$ 19,689â€‹$ -â€‹$ -Commercial paperâ€‹â€‹ -â€‹â€‹ 7,594â€‹â€‹ -Certificates of depositâ€‹â€‹ -â€‹â€‹ 1,057â€‹â€‹ -Total cash equivalentsâ€‹â€‹ 19,689â€‹â€‹ 8,651â€‹â€‹ -â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Marketable securities:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Certificates of depositâ€‹â€‹ -â€‹â€‹ 5,893â€‹â€‹ -Commercial paperâ€‹â€‹ -â€‹â€‹ 35,973â€‹â€‹ -Corporate debt securitiesâ€‹â€‹ -â€‹â€‹ 3,370â€‹â€‹ -U.S. government securitiesâ€‹â€‹ -â€‹â€‹ 7,298â€‹â€‹ -Total marketable securitiesâ€‹â€‹ -â€‹â€‹ 52,534â€‹â€‹ -Total financial assetsâ€‹$ 19,689â€‹$ 61,185â€‹$ -â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹DecemberÂ 31,Â 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹AssetsÂ â€‹Â Â Â â€‹Â Â Â â€‹Â Â Cash equivalents:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Money market fundsâ€‹$ 13,763â€‹$ -â€‹$ -Commercial paperâ€‹â€‹ -â€‹â€‹ 2,670â€‹â€‹ -Corporate debt securitiesâ€‹â€‹ -â€‹â€‹ 1,680â€‹â€‹ -Total cash equivalentsâ€‹â€‹ 13,763â€‹â€‹ 4,350â€‹â€‹ -â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Marketable securities:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Certificates of depositâ€‹â€‹ -â€‹â€‹ 10,956â€‹â€‹ -Commercial paperâ€‹â€‹ -â€‹â€‹ 34,606â€‹â€‹ -Corporate debt securitiesâ€‹â€‹ -â€‹â€‹ 22,940â€‹â€‹ -U.S. government securitiesâ€‹â€‹ -â€‹â€‹ 16,005â€‹â€‹ -U.S. government agency securitiesâ€‹â€‹ -â€‹â€‹ 8,078â€‹â€‹ -Total marketable securitiesâ€‹â€‹ -â€‹â€‹ 92,585â€‹â€‹ -Total financial assetsâ€‹$ 13,763â€‹$ 96,935â€‹$ -â€‹â€‹Non-Financial InstrumentsLong-lived non-financial assets are measured at fair value on a nonrecurring basis for purposes of calculating impairment using Level 3 inputs as defined in the fair value hierarchy. The fair value of long-lived assets using Level 3 inputs is determined by estimating the amount and timing of net future cash flows (which are unobservable inputs) and discounting them using a risk-adjusted rate of interest. Significant increases or decreases in actual cash flows may result in valuation changes.17Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsThe

following non-financial instruments were measured at fair value, on a nonrecurring basis, during the three and nine months ended SeptemberÂ 30,Â 2024. The significant assumptions utilized, which relate to future net cash flows, are further described in Note 9:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Fair Value Measurements as of SeptemberÂ 30,Â 2024â€‹Three months ended SeptemberÂ 30,Â 2024â€‹Nine months ended SeptemberÂ 30,Â 2024(in thousands)â€‹Level 1â€‹Level 2â€‹Level 3â€‹Impairment LossesProperty and equipment, net$ -$ -$ 1,708$ 2,279$ 2,279Right of use assetsâ€‹ -â€‹ -â€‹ 1,679â€‹ 2,516â€‹ 2,516Other assetsâ€‹ -â€‹ -â€‹ 200â€‹ -â€‹ 438Total$ -$ -$ 3,587$ 4,795$ 5,233â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹6. Property and Equipment, Netâ€‹Property and equipment, net, consists of the following:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹(in thousands)â€‹SeptemberÂ 30,Â 2024â€‹DecemberÂ 31,Â 2023Laboratory equipment$ 10,021â€‹$ 10,065Office equipmentâ€‹ 119â€‹â€‹ 119Computer hardware and softwareâ€‹ 1,097â€‹â€‹ 1,077Furniture and fixturesâ€‹ 419â€‹â€‹ 419Leasehold improvementsâ€‹ 7,386â€‹â€‹ 10,213Construction in progressâ€‹ -â€‹â€‹ 638Total property and equipmentâ€‹ 19,042â€‹â€‹ 22,531Accumulated depreciation and amortizationâ€‹ (9,006)â€‹â€‹ (7,236)â€‹$ 10,036â€‹$ 15,295â€‹â€‹â€‹â€‹Depreciation expense was $0.8 million and $1.0 million for the three months ended SeptemberÂ 30,Â 2024 and 2023, respectively.â€‹Depreciation expense was $2.4 million and $2.9 million for the nine months ended SeptemberÂ 30,Â 2024 and 2023, respectively.â€‹â€‹7.Â Accrued Expenses and Other Current LiabilitiesAccrued expenses and other current liabilities consisted of the following:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹(in thousands)Â Â Â Â SeptemberÂ 30,Â 2024Â Â Â Â DecemberÂ 31,Â 2023Professional feesâ€‹$ 510â€‹$ 1,176Compensation and related benefitsâ€‹Â 3,964â€‹Â 6,636Research and developmentâ€‹Â 1,255â€‹Â 1,858Litigation accrualâ€‹â€‹ 1,000â€‹â€‹ â€”Amount due to Catalent in connection with Amended Catalent Agreementsâ€‹Â â€”â€‹Â 2,000â€‹â€‹$ 6,729â€‹$ 11,670â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹18Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statements8. Gemma License AgreementOn July 31, 2024, the Company entered into a series of sublicense agreements with Gemma in connection with the outlicense of PBGM01 for the treatment of GM1 gangliosidosis, or GM1, PBKR03 for the treatment of Krabbe disease, and PBML04 for the treatment of metachromatic leukodystrophy, or MLD, collectively the Outlicensed Programs, and such agreements, the Gemma Sublicenses. Pursuant to the Gemma Sublicenses, the Company is entitled to receive (i) initial payments of $10.0 million for licenses and clinical product supply, $5.0 million of which was received in the three months ended September 30, 2024, and $5.0 million of which is due in December 2024; (ii) up to an additional $10.0 million contingent on the completion by Gemma of certain business milestones; (iii) up to an additional $114.0 million in development and commercial milestone payments; and (iv) single digit royalties as a percentage of annual worldwide net sales, in exchange for sublicenses to relevant intellectual property, transfer of regulatory dossiers and transfer of clinical trial materials and product supply related to the Outlicensed Programs. Gemma will be responsible for all payments due to Penn under the Companyâ€™s research, collaboration and licensing agreement with Penn, or the Penn License Agreement, related to the Outlicensed Programs. On July 31, 2024 the Company also entered into a transition, services agreement with Gemma, or the Transition Services Agreement, pursuant to which, the Company will provide transitional services at cost to Gemma for a period of up to six months from the effective date, and will be entitled to reimbursement for transitional services performed retroactively from March 1, 2024 to July 31, 2024, related to the transfer of the Outlicensed Programs. As Gemma is a newly-formed company with a limited history of operations, the Company will not recognize revenue under ASC 606 until the Company either (i) has received payment and there are no remaining obligations to transfer goods and services under the Gemma Sublicenses and Transition Services Agreement (as payments received by Gemma are nonrefundable), or (ii) concludes that substantially all of the transaction price is collectible. As of SeptemberÂ 30,Â 2024, the Company has received an initial payment of $5.0 million associated with the aggregate $10.0 million of payments to be made under the Gemma Sublicenses for licenses and clinical product supply. The Company recorded the $5.0 million received as non-refundable sublicense payments received on the balance sheet as of SeptemberÂ 30,Â 2024, as the criteria set forth above has not yet been met.9. Leasesâ€‹2005 Market Street Lease Agreementâ€‹The Company is party to a lease agreement for office space, or the 2005 Market Street Lease Agreement, in Philadelphia, Pennsylvania. Under the 2005 Market Street Lease Agreement, the Company leased approximately 37,000 square feet. The 2005 Market Street Lease Agreement commenced in February 2021 and is expected to expire in December 2031. The Company has an option to extend the term of the 2005 Market Street Lease Agreement by two additional terms of five years each. The Company has an option to early terminate the 2005 Market Street Lease Agreement as of April 2029, given notice is provided to the landlord no less than fifteen months prior to April 2029. The optional extension and termination terms were not recognized as part of the Companyâ€™s measurement of the ROU asset and operating lease liability as of SeptemberÂ 30,Â 2024. During 2023 the Company subleased all of the space at 2005 Market Street as further described in Sublease Agreement A and Sublease Agreement B below.â€‹Sublease Agreement Aâ€‹On August 7, 2023, the Company entered into a sublease agreement with a counterparty, or Sublessee A, to sublease approximately 8,000 square feet of the 2005 Market Street Lease Agreement, or Sublease Agreement A. This sublease term began on November 1, 2023, and continues through March 31, 2029. In the event the Company does not elect its early termination option under the 2005 Market Street Lease Agreement, Sublessee A has an option to extend the sublease agreement through November 30, 2031. The base sublease rent is $0.1 million per year and increases by 2.75% annually through the expiration of the agreement. Additionally, Sublessee A is required to pay the portion of the 19Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementscommon area maintenance expenses, operating expenses and use and occupancy taxes which the Company is required to pay under the 2005 Market Street Lease Agreement.â€‹Pursuant to ASC Topic 842, Leases, or ASC 842, the Company concluded the sublease is a separate lease, as the Company was not relieved of the primary obligation under the 2005 Market Street Lease Agreement. The Company continues to account for the 2005 Market Street Lease Agreement as a lessee and in the same manner as prior to the execution of Sublease Agreement A. The Company accounted for Sublease Agreement A as the lessor, and concluded the lease qualified as an operating lease, as it did not meet the criteria of a sales-type or direct financing lease.â€‹As a result of Sublease Agreement A, in 2023 the Company determined an impairment indicator was present. The Company compared the estimated undiscounted cash flows to the carrying value of the asset group, which includes ROU assets, leasehold improvements, and other property and equipment allocable to Sublease Agreement A. The Company concluded the carrying value of the asset group was not recoverable as it exceeded the estimated undiscounted cash flows. The Company calculated the amount of impairment using a discounted cash flow model to calculate the fair value of the asset group which incorporated the net identifiable cash flows for the term of Sublease Agreement A, including an estimate for cash flows in the residual period, and an estimated borrowing rate of a market participant subtenant. The impairment charge was recorded as of the sublease execution date.â€‹Sublease Agreement Bâ€‹On September 29, 2023, the Company entered into a sublease agreement with a counterparty, or Sublessee B, to sublease approximately 29,000 square feet of the 2005 Market Street Lease Agreement, or Sublease Agreement B. This sublease term began on March 1, 2024, and continues through August 2026. Sublessee B has an option to extend the term of the sublease agreement through March 31, 2029. The base sublease rent is $0.9 million per year for the entire term of the sublease. Additionally, Sublessee B is required to pay applicable use and occupancy taxes but is not obligated to make payments for operating expenses and common area maintenance expenses which the Company is required to pay under the 2005 Market Street Lease Agreement.â€‹Pursuant to ASC 842, the Company concluded the sublease is a separate lease, as the Company was not relieved of the primary obligation under the 2005 Market Street Lease Agreement. The Company continues to account for the 2005 Market Street Lease Agreement as a lessee and in the same manner as prior to the execution of the Sublease Agreement B. The Company accounted for Sublease Agreement B as the lessor, and concluded the lease qualified as an operating lease, as it did not meet the criteria of a sales-type or direct financing lease.â€‹As a result of Sublease Agreement B, in 2023 the Company determined an impairment indicator was present. The Company compared the estimated undiscounted cash flows to the carrying value of the asset group, which includes ROU assets, leasehold improvements, and other property and equipment allocable to Sublease Agreement B. The Company concluded the carrying value of the asset group was not recoverable as it exceeded the estimated undiscounted cash flows. The Company calculated the amount of impairment using a discounted cash flow model to calculate the fair value of the asset group which incorporated the net identifiable cash flows for the term of Sublease Agreement B, including an estimate for cash flows in the residual period, and an estimated borrowing rate of a market participant subtenant. The impairment charge was recorded as of the sublease execution date.â€‹1835 Market Street Sublease Agreementâ€‹On February 20, 2024, the Company entered into a sublease agreement with a counterparty, or the 1835 Market Street Sublease Agreement. Under the 1835 Market Street Sublease Agreement, the Company subleased approximately 16,000 square feet of office space in Philadelphia, Pennsylvania. The sublease term began on March 26, 2024 and expires on September 30, 2025. The Company has the option to extend the term of the sublease agreement through February 28, 2029. The base sublease rent is $0.3 million per year for the original 18-month term of the sublease. Additionally, the Company is required to pay utility costs associated with the subleased premises. The optional extension was not 20Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementsrecognized as part of the Companyâ€™s measurement of the ROU asset and operating lease liability as of SeptemberÂ 30,Â 2024.â€‹Laboratory Lease Agreementâ€‹The Company is also party to a lease agreement for laboratory space, or the Laboratory Lease Agreement, in Hopewell, New Jersey. The laboratory is focused on state-of-the-art analytical capabilities, assay development and validation, and clinical product testing to support both viral vector manufacturing and clinical development. The Laboratory Lease Agreement commenced in March 2021 and is expected to expire in March 2036. The Company has an option to extend the term of the Laboratory Lease Agreement by up to two five-year terms. This option to extend was not recognized as part of the Company's measurement of the ROU asset and operating lease liability as of SeptemberÂ 30,Â 2024. â€‹Hopewell Sublease Agreementâ€‹On September 4, 2024, the Company entered into a sublease agreement with a counterparty, or Sublessee C, to sublease approximately 3,200 square feet, or 5% of its approximately 62,000 feet of leased laboratory space under the Laboratory Lease Agreement, or Hopewell Sublease Agreement. This sublease term began on September 11, 2024 and expires on December 31, 2029. Sublessee C has the option to extend the term of the sublease through December 2032. The base sublease rent is $0.1 million per year and increases by 2.5% annually through the expiration of the Hopewell Sublease Agreement. Additionally, Sublessee C is required to pay the portion of the common area maintenance expenses, operating expenses, and use and occupancy taxes that the Company is required to pay under the Laboratory Lease Agreement.â€‹Pursuant to ASC 842, the Company concluded the sublease is a separate lease, as the Company was not relieved of the primary obligation under the Laboratory Lease Agreement. The Company continues to account for the Laboratory Lease Agreement as a lessee and in the same manner as prior to the execution of the Hopewell Sublease Agreement. The Company accounted for the Hopewell Sublease Agreement as the lessor, and concluded the lease qualified as an operating lease, as it did not meet the criteria of a sales-type or direct financing lease.â€‹As a result of actions in connection with previous announcements in (i) July of 2023, for an organizational redesign, and (ii) August of 2024, for the outlicense of PBGM01 for the treatment of GM1 gangliosidosis, PBKR03 for the treatment of Krabbe disease, and PBML04 for the treatment of metachromatic leukodystrophy, and the execution of the Hopewell Sublease Agreement, the Company determined triggering events were present, primarily related to changes in how underlying assets were being used in operations. As a result, the Company reassessed the asset groups related to its laboratory space under the Laboratory Lease Agreement, which resulted in changes to the Companyâ€™s identified asset groups. The Company determined whether an impairment indicator was present for each of the new asset groups. Where an impairment indicator was present, the Company compared the estimated undiscounted cash flows to the carrying value, which includes ROU assets, leasehold improvements, and other property and equipment allocable to the laboratory space for those asset groups. The Company concluded the carrying values of certain asset groups were not recoverable as it exceeded the estimated undiscounted cash flows. The Company calculated the amount of impairment on those asset groups using a discounted cash flow model to calculate the fair value of the asset group which incorporated the net identifiable cash flows for the term of the Hopewell Sublease Agreement, including an estimate for cash flows in the residual period, and an estimated borrowing rate of a market participant subtenant. As a result, certain asset groups were impaired and the Company recognized impairment expense of $4.8 million, including $2.5 million for the ROU assets and $2.3 million for the property and equipment during the three and nine months ended SeptemberÂ 30,Â 2024.â€‹â€‹21Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsThe following table summarizes future minimum lease payments for the Companyâ€™s lessee operating leases, which comprises the 2005 Market Street Lease Agreement, 1835 Market Street Sublease Agreement, and the Laboratory Lease Agreement. The below table does not include expected cash inflows related to Sublease Agreement A, Sublease Agreement B, and Hopewell Sublease Agreement as the Company was not relieved of its primary obligation under the 2005 Market Street Lease Agreement and Laboratory Lease Agreement:â€‹â€‹â€‹â€‹â€‹(in thousands)â€‹Â Â Â Â Â Â Â Â Â 2024â€‹$ 9692025â€‹Â 3,8832026â€‹Â 3,7572027â€‹Â 3,8632028â€‹Â 3,973Thereafterâ€‹Â 25,706Total undiscounted lease paymentsâ€‹â€‹ 42,151Less: imputed interestâ€‹â€‹ (16,333)Total lease liabilitiesâ€‹$ 25,818â€‹â€‹The following table summarizes lease expense by lease type that was recognized during the three and nine months ended SeptemberÂ 30,Â 2024 and 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Three Months Ended â€‹Nine Months Ended ($ in thousands)â€‹SeptemberÂ 30,Â 2024â€‹SeptemberÂ 30,Â 2023â€‹SeptemberÂ 30,Â 2024â€‹SeptemberÂ 30,Â 2023Operating lease costâ€‹$ 904â€‹$ 831â€‹$ 2,644â€‹$ 2,492Variable lease costâ€‹â€‹ 530â€‹â€‹ 644â€‹â€‹ 1,644â€‹â€‹ 1,570â€‹â€‹$ 1,434â€‹$ 1,475â€‹$ 4,288â€‹$ 4,062â€‹The following table shows the weighted average discount rate and weighted average remaining lease term of the operating leases:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Nine Months Ended â€‹Nine Months Ended ($ in thousands)â€‹SeptemberÂ 30,Â 2024â€‹SeptemberÂ 30,Â 2023Weighted-average discount rateâ€‹â€‹ 9.7%â€‹â€‹ 9.7%Weighted-average remaining lease term (years)â€‹â€‹ 10.4â€‹â€‹ 11.5â€‹â€‹The cash paid for amounts included in the measurement of our operating lease liabilities for the nine months ended SeptemberÂ 30,Â 2024 and 2023 were $2.8 million and $2.6 million, respectively, recorded in operating cash flows.â€‹The following table summarizes sublease income that was recognized in other income (expense), net during the three and nine months ended SeptemberÂ 30,Â 2024 and 2023:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Three Months Ended â€‹Nine Months Ended ($ in thousands)â€‹SeptemberÂ 30,Â 2024â€‹SeptemberÂ 30,Â 2023â€‹SeptemberÂ 30,Â 2024â€‹SeptemberÂ 30,Â 2023Sublease rental incomeâ€‹$ 332â€‹$ â€”â€‹$ 632â€‹$ â€”â€‹$ 332â€‹$ â€”â€‹$ 632â€‹$ â€”â€‹$ 10.Â Commitments and ContingenciesAmended and Restated Research, Collaboration and License Arrangement with PennIn connection with the transfer of the Outlicensed Programs (GM1, Krabbe, and MLD), the Company restructured its research, collaboration and licensing agreement with Penn, as amended, previously the Penn Agreement and now 22Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementsreferred to as the Penn License Agreement. Pursuant to the Penn License Agreement, as of July 31, 2024, the Company (i) terminated the funding of discovery research programs; (ii) terminated the research and exploratory research programs; (iii) terminated the remaining eight options it had for future central nervous system, or CNS, indications; (iv) terminated the transaction fee payable to Penn in the event of certain corporate transactions; and (v) retained its current exclusive and non-exclusive licenses to its programs in FTD, GM1, Krabbe and MLD and certain platform technologies resulting from the discovery programs that it funded.For the Companyâ€™s licensed programs in FTD, GM1, Krabbe and MLD, the Penn License Agreement requires that it make payments of up to $16.5 million per product candidate. Each payment will be due upon the achievement of specific development milestone events by such licensed product for a first indication, reduced development milestone payments for the second and third indications and no development milestone payments for subsequent indications. In addition, on a product-by-product basis, the Company is obligated to make up to $55.0 million in sales milestone payments on each licensed product based on annual worldwide net sales of the licensed product in excess of defined thresholds. Pursuant to the Gemma Sublicenses, Gemma is responsible for the payments to Penn related to the Outlicensed Programs. Upon successful commercialization of a product using the licensed technology, the Company is obligated to pay to Penn, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) in the mid-single digits percentage on annual worldwide net sales of such licensed product. In addition, other than the Gemma Sublicenses, the Company is obligated to pay to Penn a percentage of sublicensing income, ranging from the mid-single digits to low double digits, for sublicenses under the Penn License Agreement. The agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the later of (i) the expiration of the last valid claim of the licensed patent rights that covers the exploitation of such licensed product in such country, and (ii) the expiration of the royalty period. Pursuant to the Gemma Sublicenses, Gemma is responsible for the payments to Penn related to the Outlicensed Programs.Gemma - Research, Collaboration and License Agreement In connection with the transfer of the Outlicensed Programs, on July 31, 2024, the Company entered into a research, collaboration and license agreement with Gemma, or the Gemma Collaboration Agreement. Pursuant to the Gemma Collaboration Agreement, (i) Gemma will conduct certain preclinical and IND-enabling work for the Companyâ€™s active research program in Huntingtonâ€™s disease and a currently paused research program in Temporal Lobe Epilepsy, or TLE, which were previously being conducted by Penn under the Penn Agreement and (ii) Gemma will grant the Company options to conduct mutually-agreed research programs in four new CNS indications.The Gemma Collaboration Agreement requires the Company to make payments of up to (i) $16.5 million per product candidate in the aggregate for Huntingtonâ€™s disease and any future CNS indications available to the Company under its four options and (ii) $39.0 million per product candidate in the aggregate arising from the research program for TLE. Each payment will be due upon the achievement of specific development milestone events by such licensed product for a

first indication, reduced development milestone payments for the second and third indications and no development milestone payments for subsequent indications. In addition, on a product-by-product basis, the Company is obligated to make up to $55.0 million in sales milestone payments on each licensed product based on annual worldwide net sales of the licensed product in excess of defined thresholds.Upon successful commercialization of a product using the licensed technology, the Company is obligated to pay to Gemma, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) in the mid-single digits percentage on annual worldwide net sales of such licensed product. In addition, the Company is obligated to pay to Gemma a percentage of sublicensing income, ranging from the mid-single digits to low double digits, for sublicenses under the Gemma Collaboration Agreement. The agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the later of (i) the expiration of the last valid claim of the licensed patent rights that covers the exploitation of such licensed product in such country, and (ii) the expiration of the royalty period. 23Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsIf the Company was to exercise any of the four options, it would owe Gemma a non-refundable aggregate fee of $1.0 million per product indication, with $0.5 million due upfront and another $0.5 million fee owed upon a further developmental milestone. The Company has also entered into the Gemma Sublicenses and Transition Services Agreement as described in Note 8.The Gemma Sublicenses, the Transition Services Agreement, and the Gemma Collaboration Agreement are collectively referred to as the Outlicense Transaction Agreements.Catalent Agreements In June 2019, the Company entered into a collaboration agreement, or the Collaboration Agreement, with Catalent Maryland, a unit of Catalent, Inc., or Catalent. As part of the Collaboration Agreement, the Company was required to pay an annual fee for five years ending in 2025 for the exclusive use of a dedicated clean room suite, or the Clean Room Suite.In April 2020, the Company entered into a development services and clinical supply agreement, or the Manufacturing and Supply Agreement, with Catalent to secure clinical scale manufacturing capacity for batches of active pharmaceutical ingredients for the Companyâ€™s gene therapy product candidates. Under the terms of the Manufacturing and Supply Agreement, Catalent agreed to manufacture batches of drug product for the Companyâ€™s gene therapy product candidates at the Clean Room Suite at a Catalent facility provided for in the Collaboration Agreement. The Manufacturing and Supply Agreement provided for a term of five years. The Manufacturing and Supply Agreement also included minimum annual purchase commitments.Under both the Collaboration Agreement and the Manufacturing and Supply Agreement, the Company had an annual minimum commitment of $10.6 million per year owed to Catalent for five years from November 2020 subject to certain inflationary adjustments. On March 31, 2023, the Company entered into certain letter agreements, the Letter Agreements, amending each of (i) the Collaboration Agreement and (ii) the Manufacturing and Supply Agreement, together with the Collaboration Agreement, the Original Catalent Agreements. On November 9, 2023, to supersede and implement the terms of the Letter Agreements, the Company entered into an amended and restated collaboration agreement and an amended and restated manufacturing and supply agreement, together the Amended Catalent Agreements.The Amended Catalent Agreements eliminate the minimum annual purchase obligation and the obligation to pay an annual fee for use of the Clean Room Suite, thereby eliminating the annual minimum commitment of $10.6 million per year owed to Catalent through November 2025 under the Original Catalent Agreements. In consideration of this, the Company had an obligation to make aggregate payments to Catalent of $6.0 million between June 30, 2023 and May 1, 2024. As of SeptemberÂ 30,Â 2024, the Company has made all payments related to this obligation under the Amended Catalent Agreements.The Amended Catalent Agreements extend the term of the Original Catalent Agreements until November 6, 2030, and establish a limited exclusive relationship between the Company and Catalent for the manufacture of bulk drug substance and drug product for the Companyâ€™s adeno-associated virus delivery therapeutic product candidates for the treatment of frontotemporal dementia, or FTD, and GM1. The limited exclusive relationship under the Amended Catalent Agreements converts to a non-exclusive relationship (i) in the event Catalent fails to meet certain performance standards and (ii) following certain conditional events related to the divestiture by the Company of either FTD or GM1, in which case, if such events occur, the Company would pay Catalent certain fees. The outlicense of GM1 to Gemma under the Outlicense Transaction Agreements, and subsequent business decisions implemented by Gemma in their sole discretion, could be considered an event related to the divesture of GM1 under the Amended Catalent Agreements and require us to make payment of certain fees to Catalent, for which fees are immaterial.24Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial StatementsImmediately prior to the execution of the Letter Agreements, the Company had a $5.3 million prepaid asset related to upfront payments made to secure the Clean Room Suite. In connection with the Letter Agreements, the Company no longer has exclusive access to the Clean Room Suite at Catalent and, as a result, the Company recognized an expense of $5.3 million related to the elimination of the prepaid asset during the nine months ended SeptemberÂ 30,Â 2023.The Company classified the $11.3 million of expenses, which comprises of $6.0 million in aggregate payments due to Catalent and the $5.3 million elimination of the prepaid asset, as general and administrative expense within the statement of operations for the nine months ended SeptemberÂ 30,Â 2023, as both amounts did not directly relate to the future advancement of the Companyâ€™s research and development programs.LitigationIn the normal course of business, the Company from time to time is named as a party to legal claims and actions. The Company records a loss contingency reserve for a legal proceeding when the potential loss is considered probable and can be reasonably estimated. Subsequent to September 30, 2024, the Company received a jury verdict for one outstanding matter and has recorded $1.0 million for loss contingencies as general and administrative expense within the statement of operations for the three and nine months ended September 30, 2024. See â€œNote 12 â€“Subsequent Eventsâ€ for additional information related to the claim.Employment AgreementsThe Company has employment agreements with certain key personnel providing for up to 18 months of salary continuation, up to 150% of target annual bonus amounts, and acceleration of vesting in stock-based compensation awards in certain circumstances.11. Share-Based CompensationEquity Incentive PlanThe Company has three equity incentive plans: the 2018 Equity Incentive Plan, as amended, or the 2018 Plan, the 2020 Equity Incentive Plan, or the Incentive Plan, and the 2021 Equity Inducement Plan, or the Inducement Plan. New awards can only be granted under the Incentive Plan and the Inducement Plan. The total number of shares authorized under the Incentive Plan as of SeptemberÂ 30,Â 2024 was 15,848,867. Additionally, 3,635,337 shares previously issued under the 2018 Plan which were forfeited are available for issuance under the Incentive Plan. As of SeptemberÂ 30,Â 2024, 8,258,331 shares were available for future grants under the Incentive Plan. The number of shares of the Companyâ€™s common stock that may be issued pursuant to rights granted under the Incentive Plan shall automatically increase on January 1st of each year, commencing on January 1, 2021 and continuing for ten years, in an amount equal to five percent of the total number of shares of the Companyâ€™s common stock outstanding on December 31st of the preceding calendar year, subject to the discretion of the board of directors to determine a lesser number of shares shall be added for such year. As a result, the number of shares reserved for issuance under the Incentive Plan increased by 2,747,206 and 2,730,735 shares in January 2024 and 2023, respectively.The Incentive Plan provides for the granting of common stock, incentive stock options, nonqualified stock options, restricted stock awards, and/or stock appreciation rights to employees, directors, and other persons, as determined by the Companyâ€™s board of directors. The Companyâ€™s stock options awarded to date under the Incentive Plan vest based on a requisite service period, generally over four-year periods, and have a term of ten years.The Inducement Plan was approved by the Companyâ€™s board of directors in July 2021. The total number of shares authorized under the Inducement Plan as of SeptemberÂ 30,Â 2024 was 2,500,000. Of this amount, 1,416,200 shares were available for future grants as of SeptemberÂ 30,Â 2024. The Inducement Plan provides for the granting of nonqualified 25Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementsstock options and restricted stock awards to employees hired by the Company, as determined by the Companyâ€™s board of directors. The Companyâ€™s stock options awarded to date under the Inducement Plan vest based on requisite service period and have a term of ten years. The Companyâ€™s restricted stock units awarded to date under the Inducement Plan vest based on requisite service period and have a term based on each award agreement. The Company measures share-based awards at their grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the awards. The Company recorded share-based compensation expense in the following expense categories in its accompanying statements of operations for the period presented:â€‹Three Months Ended SeptemberÂ 30,Â â€‹Nine Months Ended SeptemberÂ 30,Â (in thousands)Â Â Â Â 2024Â Â Â Â 2023â€‹2024Â Â Â Â 2023Research and developmentâ€‹$ 535â€‹$ 1,429â€‹$ 2,078â€‹$ 4,788General and administrativeâ€‹Â 865â€‹Â 1,395â€‹Â 2,495â€‹Â 4,563â€‹â€‹$ 1,400â€‹$ 2,824â€‹$ 4,573â€‹$ 9,351â€‹The following table summarizes stock option activity for the nine months ended SeptemberÂ 30,Â 2024:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Â Â Â Â â€‹â€‹Â Â Â Â â€‹â€‹Â Â Â Â Weightedâ€‹â€‹â€‹â€‹Weightedâ€‹averageâ€‹â€‹â€‹â€‹averageâ€‹remainingâ€‹â€‹NumberÂ ofâ€‹exerci at JanuaryÂ 1, 2024Â 9,290,308Â $ 5.63Â 8.0GrantedÂ 4,789,046â€‹â€‹ 1.37Â Â Â ExercisedÂ (31,925)â€‹â€‹ 1.08Â Â Â ForfeitedÂ (2,035,378)â€‹â€‹ 5.95Â Â Â ExpiredÂ â€”â€‹â€‹Outstanding at SeptemberÂ 30,Â 2024Â 12,012,051â€‹$ 3.89Â 7.7Vested and exercisable at SeptemberÂ 30,Â 2024Â 5,901,349â€‹$ 6.27Â 6.3Vested or expected to vest at SeptemberÂ 30,Â 2024Â 12,012,051â€‹$ 3.89Â 7.7â€‹The weighted average grant date fair value of options granted was $1.03 and $0.82 for the nine months ended SeptemberÂ 30,Â 2024 and 2023, respectively. As of SeptemberÂ 30,Â 2024, the total unrecognized compensation expense related to unvested stock option awards was $6.9Â million, which the Company expects to recognize over a weighted average period of 2.3Â years. The fair value of each option was estimated on the date of grant using the weighted average assumptions in the table below:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Nine Months Ended SeptemberÂ 30,Â â€‹â€‹2024â€‹2023Expected volatilityâ€‹ 88.4%Â Â â€‹ 92.6%Riskâ€‘free interest rateâ€‹ 4.2%â€‹ 3.6%Expected termâ€‹ 6.0yearsâ€‹ 6.0yearsExpected dividend yieldâ€‹ â€”â€‹â€‹ â€”â€‹â€‹Restricted Stock UnitsThe Company issues RSUs to employees that vest over periods of time as determined by the board of directors. Any unvested shares are forfeited upon termination of services. The fair value price of the RSUs is equal to the fair market value of the Companyâ€™s common stock on the date of grant. Compensation expense is recognized on a straight-line basis over the vesting period of the RSUs.26Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementsâ€‹The following table summarizes activity related to RSU awards during the nine months ended SeptemberÂ 30,Â 2024:â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Â Â Â Â â€‹â€‹Â Â Â Â â€‹Weighted average â€‹â€‹Â NumberÂ ofÂ sharesÂ â€‹grant date fair valueUnvested balance at January 1,Â 2024â€‹Â 927,000Â $ 2.37Grantedâ€‹Â 147,500Â â€‹ 1.29Vestedâ€‹â€‹ (692,666)â€‹â€‹ 2.36Forfeitedâ€‹Â (51,667)Â â€‹ 2.87Unvested balance at SeptemberÂ 30,Â 2024â€‹Â 330,167Â $ 1.83â€‹As of SeptemberÂ 30,Â 2024, the total unrecognized expense related to all RSUs was $0.2Â million, which the Company expects to recognize over a weighted-average period of 0.5Â years.â€‹Employee Stock Purchase PlanThe Companyâ€™s 2020 Employee Stock Purchase Plan, or the ESPP, became effective on February 28, 2020. The ESPP authorizes the issuance of up toÂ 1,981,766 shares of the Companyâ€™s common stock. Of this amount, 1,379,590 were available for future grants as of SeptemberÂ 30,Â 2024. The number of shares of the Companyâ€™s common stock that may be issued pursuant to rights granted under the ESPP shall automatically increase on JanuaryÂ 1st of eachÂ year and continuing for ten years, in an amount equal to oneÂ percent of the total number of shares of the Companyâ€™s common stock outstanding on DecemberÂ 31st of the preceding calendarÂ year, subject to the discretion of the board of directors to determine a lesser number of shares shall be added for suchÂ year. The board of directors determined the shares authorized for issuance under the ESPP would not be increased in 2024.Under the ESPP, eligible employees can purchase the Companyâ€™s common stock through accumulated payroll deductions at such times as are established by the board of directorâ€™s Compensation Committee. Eligible employees may purchase the Companyâ€™s common stock at 85% of the lower of the fair market value of the Companyâ€™s common stock on the first day of the offering period or on the last day of the offering period. The offering periods under the ESPP have a duration of six months, with periods ending in May and November of each calendar year. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not accrue rights to purchase more than $25,000 worth of the Companyâ€™s common stock for each calendarÂ year in which such right is outstanding or purchase more than 4,000 shares of the Companyâ€™s common stock in any single offering period.In accordance with the guidance in ASC Topic 718-50,Â CompensationÂ â€“ Stock Compensation, the ability to purchase shares of the Companyâ€™s common stock at 85% of the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, share-based compensation expense is determined based on the optionâ€™s grant-date fair value as estimated by applying the Black-Scholes option-pricing model and is recognized over the withholding period.12.Â Subsequent EventsThe Company is currently a defendant in litigation with a former employee in the Court of Common Pleas of Philadelphia County (Commerce Division), or the Court, relating to a claim of breach of contract and violation of the Pennsylvania Wage Payment and Collection Law, or the Claims. The plaintiff claims that, pursuant to an alleged settlement agreement reached on February 3, 2020, the Company agreed to issue plaintiff 150,000 shares of its common stock and that such shares would not be subject to the reverse stock split implemented by the Company in connection with its initial public offering on February 14, 2020. The plaintiffâ€™s claim is for an amount in the mid-single digit millions of dollars. The Company disagrees with the allegations that there was ever a binding settlement agreement or that any shares would not be subject to the reverse stock split. In October 2023, the Court denied both the Companyâ€™s and the plaintiffâ€™s motions for summary judgement and a trial date was set for October 2024. The Company has 27Table of ContentsPassage Bio, Inc.Notes to Unaudited Interim Financial Statementsvigorously defended against these claims. On October 28, 2024, the Court entered a directed verdict in favor of the Company on the Pennsylvania Wage Payment and Collection Claim, and on October 29, the jury found for the plaintiff in the amount of $1.0 million on the breach of contract Claim, which the Company has accrued for and recognized in general and administrative expenses for the three and nine months ended September 30, 2024. The jury verdict is subject to post-trial motions and the Company will consider whether to appeal if its motions are denied and judgment is entered on the verdict.â€‹â€‹â€‹28Table of ContentsItemÂ 2. Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations.You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on FormÂ 10-Q. In addition to historical financial information, this discussion and analysis contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled â€œRisk Factorsâ€ under PartÂ II, ItemÂ 1A below. Overview and PipelineWe are a clinical stage genetic medicines company on a mission to improve the lives of patients with neurodegenerative diseases. Our primary focus is the development and advancement of cutting-edge, one-time gene therapies designed to target critical underlying pathologies in these conditions. We believe we have developed a differentiated approach to developing treatments for central nervous system, or CNS, disorders that allows us to select and advance product candidates with a higher probability of technical and regulatory success. Our lead clinical product candidate, PBFT02, seeks to elevate progranulin levels to enhance lysosomal function and slow disease progression across a variety of neurodegenerative diseases. PBFT02 utilizes an adeno-associated virus serotype 1, or AAV1, capsid to deliver a functional granulin gene, or GRN, encoding progranulin, or PGRN, to the brain via intra cisterna magna, or ICM, administration. The lead indication for PBFT02 is frontotemporal dementia, or FTD, caused by progranulin deficiency, or FTD-GRN. We believe this clinical product candidate has the potential to provide patients with significantly improved outcomes given the rigorous capsid and transgene selection process, and our chosen route of ICM administration, which provides the potential for enhanced benefits due to widespread vector delivery to the brain and spinal cord and an improved safety profile compared with systemic administration due to the lower doses required.We are currently studying PBFT02 in FTD-GRN, for which there are currently no approved disease-modifying therapies. In addition to the continued clinical development of PBFT02 to treat FTD-GRN, we intend to pursue PBFT02 in additional adult neurodegenerative diseases where we believe increasing PGRN levels could provide benefit. Third-party preclinical studies have shown that increased PGRN levels reduce the pathologic accumulation of TAR DNA binding protein 43, or TDP-43. TDP-43 pathology is a hallmark of multiple neurodegenerative conditions, including FTD due to mutations in the C9orf72 gene, or FTD-C9orf72, approximately 95% of sporadic amyotrophic lateral sclerosis, or ALS, and approximately 50% of sporadic FTD. Additionally, we believe restoration of PGRN has the potential to modulate Alzheimerâ€™s disease, or AD, in patients that are carriers of the PGRN-lowering GRN rs5848 single nucleotide polymorphism, or SNP. Individuals with this polymorphism have reduced PGRN levels and are at an increased risk for AD. We received positive regulatory feedback on the clinical pathway to treating FTD-C9orf72 patients with PBFT02 and plan to initiate dosing in the first half of 2025. We expect to obtain regulatory feedback on the clinical pathway to treating ALS patients with PBFT02 in the second half of 2024.Research DevelopmentsOn July 31, 2024, we entered into a series of sublicense agreements with Gemma Biotherapeutics, Inc., or Gemma, a newly formed genetic medicines company co-founded by Dr. James Wilson, who also serves as a consultant to the Company as a Scientific Advisor in connection with the outlicense of PBGM01 for the treatment of GM1 gangliosidosis, or GM1, PBKR03 for the treatment of Krabbe disease, and PBML04 for the treatment of metachromatic leukodystrophy, or MLD, collectively the Outlicensed Programs and such agreements, the Gemma Sublicenses. Pursuant to the Gemma Sublicenses, we will receive (i) initial payments of an aggregate of $10.0 million for licenses and clinical product supply; (ii) up to an additional $10.0 million contingent on the completion by Gemma of certain business milestones; (iii) up to an

additional $114.0 million in development and commercial milestone payments; and (iv) single digit royalties as a percentage of annual worldwide net sales in exchange for sublicenses to relevant intellectual property, transfer of regulatory dossiers and transfer of clinical trial materials and product supply related to the Outlicensed Programs. Pursuant to the Gemma Sublicenses, Gemma will also be responsible for all payments due to the Trustees of the University of Pennsylvania, or Penn, under the Penn License Agreement, as further described below, related to the 29Table of ContentsOutlicensed Programs. We also entered into a transition services agreement with Gemma, or the Transition Services Agreement, pursuant to which, we will provide transitional services at cost to Gemma for a period of up to six months from the effective date, and be entitled to reimbursement for transitional services performed retroactively from March 1, 2024, related to the transfer of the Outlicensed Programs. â€‹We also entered into a research, collaboration and license agreement with Gemma, or the Gemma Collaboration Agreement, pursuant to which (i) Gemma will conduct certain preclinical and IND-enabling work for our active research program in Huntingtonâ€™s disease and a currently paused research program in Temporal Lobe Epilepsy, or TLE, which were previously being conducted by Penn under the Penn Agreement and (ii) Gemma will grant us options to conduct new research programs in four new CNS indications.We refer to the Gemma Sublicenses, the Transition Services Agreement, and the Gemma Collaboration Agreement, collectively, as the Outlicense Transaction Agreements.As a result of the Outlicense Transaction Agreements, we also entered into an Amended and Restated Research, Collaboration and License Arrangement with Penn as of July 31, 2024, or the Penn License Agreement, to (i) terminate our funding of discovery research; (ii) terminate the research and exploratory research programs being conducted by Penn; (iii) terminate the remaining options we had to select new research programs in the CNS field; and (iv) terminate the transaction fee due to Penn as a result of certain corporate transactions. Prior to the execution of the Outlicense Transaction Agreements, we had a research collaboration with Pennâ€™s, Gene Therapy Program, or GTP, headed by Dr. Wilson. Under this collaboration, we progressed four product candidates sourced from our research collaboration with GTP to the clinical stage of development and had one active preclinical program in Huntingtonâ€™s disease. We have a gene therapy pipeline with the potential to address multiple neurodegenerative diseases. Our development programs consist of:â€ US/EU prevalence per third-party sourcesâ€‹PBFT02 for the Treatment of FTD-GRN â€‹We are currently developing PBFT02, which utilizes an AAV1 capsid to deliver a functional copy of GRN encoding for PGRN, for the treatment of FTD-GRN. FTD-GRN is an inheritable form of FTD caused by reductions in PGRN production due to mutations in the GRN gene. PGRN is a complex and highly conserved protein with multiple roles in cell homeostasis, neurodevelopment, and inflammation. In FTD-GRN, PGRN deficiency results in lysosomal dysfunction, neuroinflammation, and neurodegeneration. 30Table of ContentsCurrently, there are no disease-modifying therapies approved for the treatment of FTD-GRN. Based on findings in preclinical studies, we believe that PBFT02 may provide FTD-GRN patients with significantly improved outcomes. We selected the AAV1 capsid and ICM administration for PBFT02 because this approach led to extensive and robust vector delivery throughout the brain and spinal cord of non-human primates, or NHPs, and due to the higher PGRN levels in cerebrospinal fluid, or CSF, achieved using AAV1 as compared with other serotypes tested. ICM administration of AAV1 to NHPs resulted in elevated CSF levels of human PGRN when compared with CSF levels in healthy human subjects, and in excess of levels achieved in NHPs with AAVhu68 or AAV5. We have an active Investigational New Drug application, or IND, from the U.S. Food and Drug Administration, or FDA, and approved clinical trial authorizations, or CTAs, in multiple countries for PBFT02. We are conducting our upliFT-D trial, an international, multi-center, open-label, single-arm Phase 1/2 clinical trial of PBFT02 in patients with a diagnosis of symptomatic FTD-GRN. We reported biomarker data from four patients in Cohort 1 of our upliFT-D trial in December of 2023, May 2024, and September 2024. Dose 1 of PBFT02 resulted in consistent elevated levels of CSF PGRN with concentrations ranging from 10.7 to 17.3 ng/mL at 30 days post-treatment (n=5), and 21.7 to 27.3 ng/mL at 6 months post-treatment (n=2). CSF PGRN remained elevated at 12 months (n=1), reaching a level of 34.2 ng/mL. The rate of increase was 58% between one month and six months and slowed to 26% between six months and twelve months. These ranges are higher than the range found in healthy adult controls of 3.3 to 8.2 ng/mL (mean=4.8 ng/mL; n=61). In contrast, following PBFT02 treatment, plasma PGRN levels were unaltered, remaining similar to baseline concentrations and below levels found in healthy adult controls.As of August 2024, Dose 1 of PBFT02 treatment was generally well-tolerated in study participants who received an enhanced immunosuppression regimen (n=4).We have completed dosing of Cohort 1 (n=5) and have enrolled the first four patients in Cohort 2 (n=5). Based on the robust PGRN expression observed in the initial patients in Cohort 1, we are continuing to study Dose 1 in Cohort 2 of the upliFT-D trial. We expect to deliver on the following related to our upliFT-D trial for PBFT02 for the treatment of FTD-GRN:â—report 12-month follow-up data from Cohort 1 patients and interim data from Cohort 2 patients in the first half of 2025; and,â—seek regulatory feedback on pivotal trial design in the second half of 2025.â€‹The FDA has granted Orphan Drug Designation for PBFT02 for the treatment of FTD and Fast Track Designation for PBFT02 for the treatment of FTD-GRN. The European Commission has granted Orphan designation for PBFT02 for the treatment of FTD.PBFT02 for the treatment of FTD-C9orf72 and ALSWe intend to pursue PBFT02 in additional adult neurodegenerative diseases where we believe elevated PGRN levels could provide benefits. This approach stems from PGRNâ€™s pleiotropic cellular effects including the regulation of microglial activation and lysosomal function, and in particular its potential to ameliorate TDP-43 pathology. TDP-43 is a ribonucleic acid / deoxyribonucleic acid, or RNA/DNA, binding protein that normally resides in the nucleus where it regulates gene expression, RNA splicing, RNA trafficking, and mRNA turnover. Cytoplasmic TDP-43 pathology is a hallmark of multiple neurodegenerative conditions including FTD-GRN, FTD-C9orf72, approximately 95% of sporadic ALS, and approximately 50% of sporadic FTD. In these disorders, hyperphosphorylated TDP-43 accumulates in the cytoplasm of cell bodies and dendritic processes of neurons and glia, suggesting that loss of TDP-43's normal nuclear function contributes to the neurodegenerative process.The potential for benefit of increased PGRN in disorders with TDP-43 pathology has been demonstrated by third-party preclinical studies in mice and zebrafish which showed that increased PGRN levels reduced TDP-43 pathology and associated toxicities. We anticipate that elevating neuronal PGRN levels in diseases with TDP-43 pathology may provide significant benefits to patients.Â We have initiated preclinical studies to extend these initial observations.31Table of ContentsWe received positive regulatory feedback on the clinical pathway to treating FTD-C9orf72 with PBFT02 in the ongoing upliFT-D trial and expect to initiate dosing in the first half of 2025. We expect to obtain regulatory feedback on the clinical pathway to treating ALS patients with PBFT02 in the second half of 2024.PBFT02 for the treatment of ADWe believe that elevating PGRN levels has the potential to improve the course of AD in patients who carry the GRN rs5848 single nucleotide polymorphism, or GRN SNP. The GRN SNP has an allele frequency of approximately 30% and is associated with reduced PGRN levels. Its presence has been shown to confer an increased risk for AD onset. Within symptomatic AD patients, GRN SNP carriers not only have lower levels of PGRN, but also higher levels of CSF tau, which correlates with increased AD pathology in the brain and more rapid disease progression. Third party preclinical studies in animal models have demonstrated that low levels of PGRN may exacerbate AD pathology and, conversely, high levels of PGRN may reduce AD pathology. We have initiated preclinical studies in AD to extend these initial observations.Other Clinical Product CandidatesAs of July 31, 2024, we outlicensed our clinical stage pediatric programs in GM1 (PBGM01), Krabbe disease (PBKR03), and MLD (PBML04) as part of the Outlicense Transaction Agreements.Active Research ProgramsWe have one unnamed preclinical research program through the Gemma Collaboration Agreement (which was previously conducted by Penn under the Penn Agreement) and are exploring multiple potential treatment targets for Huntingtonâ€™s disease. â€‹Beyond this program, as a result of the Gemma Collaboration Agreement, we also have the option to license programs for four additional new indications in CNS diseases from Gemma.â€‹Paused Research ProgramsWe also have a research program through the Gemma Collaboration Agreement for TLE, which was previously conducted by Penn under the Penn Agreement. In order to reduce operating expenses, we have paused development of this program.Business Overviewâ€‹We were incorporated in July 2017 under the laws of the State of Delaware. Since inception, our operations have consisted primarily of conducting preclinical studies, developing licensed technology, conducting clinical trials, and manufacturing clinical supply to support clinical trials. We have incurred recurring losses, the majority of which are attributable to research and development activities, and negative cash flows from operations. Historically, we have funded our operations through the sale of convertible preferred stock and public offerings of common stock. Our net losses were $19.3 million and $27.1 million for the three months ended SeptemberÂ 30,Â 2024 and 2023, respectively, and $52.0 million and $85.3 million for the nine months ended SeptemberÂ 30,Â 2024 and 2023, respectively. As of SeptemberÂ 30,Â 2024, we had an accumulated deficit of $646.5 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant 32Table of Contentscommercialization expenses related to product manufacturing, marketing, sales and distribution. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our clinical trials and our expenditures on other research and development activities.â€‹We will need to raise substantial additional capital to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we plan to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to secure adequate additional funding, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates or delay our pursuit of potential in-licenses or acquisitions.â€‹As of SeptemberÂ 30,Â 2024, we had cash, cash equivalents and marketable securities of $84.8 million. We expect our existing cash, cash equivalents and marketable securities, combined with the remaining initial payments for the licenses and clinical product supply in connection with the Gemma Sublicenses, and expected payments in connection with the Gemma Transition Services Agreement, will enable us to fund our operating expenses and capital expenditure requirements to the end of the second quarter of 2026.Financial Operations OverviewLicense AgreementUniversity of PennsylvaniaAs a result of the Outlicense Transaction Agreements, we restructured our research, collaboration and licensing agreement with Penn, as amended, previously the Penn Agreement and now referred to as the Penn License Agreement. Pursuant to the Penn License Agreement, as of July 31, 2024, we (i) terminated the funding of discovery research programs; (ii) terminated the research and exploratory research programs; (iii) terminated the remaining eight options we had for future CNS indications; (iv) terminated the transaction fee payable to Penn in the event of certain corporate transactions; and (v) retained our current exclusive and non-exclusive licenses to our programs in FTD, GM1, Krabbe and MLD and certain platform technologies resulting from the discovery programs that we funded.For our licensed programs in FTD, GM1, Krabbe and MLD, the Penn License Agreement requires that we make payments of up to $16.5 million per product candidate. Each payment will be due upon the achievement of specific development milestone events by such licensed product for a first indication, reduced development milestone payments for the second and third indications and no development milestone payments for subsequent indications. In addition, on a product-by-product basis, we are obligated to make up to $55.0 million in sales milestone payments on each licensed product based on annual worldwide net sales of the licensed product in excess of defined thresholds. Pursuant to the Gemma Sublicenses, Gemma is responsible for the payments to Penn related to the Outlicensed Programs. Upon successful commercialization of a product using the licensed technology, we are obligated to pay to Penn, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) in the mid-single digits percentage on annual worldwide net sales of such licensed product. In addition, other than the Gemma Sublicenses, we are obligated to pay to Penn a percentage of sublicensing income, ranging from the mid-single digits to low double digits, for sublicenses under the Penn License Agreement. The agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the later of (i) the expiration of the last valid claim of the licensed patent rights that covers the exploitation of such licensed product in such country, and (ii) the expiration of the royalty period. Pursuant to the Gemma Sublicenses, Gemma is responsible for the payments to Penn related to the Outlicensed Programs.â€‹33Table of ContentsGemma - Research, Collaboration and License Agreement In connection with the transfer of the Outlicensed Programs, on July 31, 2024, we entered into a research, collaboration and license agreement with Gemma, or the Gemma Collaboration Agreement. Pursuant to the Gemma Collaboration Agreement, (i) Gemma will conduct certain preclinical and IND-enabling work for our active research program in Huntingtonâ€™s disease and a currently paused research program in TLE, which were previously being conducted by Penn under the Penn Agreement and (ii) Gemma will grant us options to conduct mutually agreed research programs in four new CNS indications.The Gemma Collaboration Agreement requires that we make payments of up to (i) $16.5 million per product candidate in the aggregate for Huntingtonâ€™s disease and any future CNS indications available to us under our four options and (ii) $39.0 million per product candidate in the aggregate arising from the research program for TLE. Each payment will be due upon the achievement of specific development milestone events by such licensed product for a first indication, reduced development milestone payments for the second and third indications and no development milestone payments for subsequent indications. In addition, on a product-by-product basis, we are obligated to make up to $55.0 million in sales milestone payments on each licensed product based on annual worldwide net sales of the licensed product in excess of defined thresholds.Upon successful commercialization of a product using the licensed technology, we are obligated to pay to Gemma, on a licensed product-by-licensed product and country-by-country basis, tiered royalties (subject to customary reductions) in the mid-single digits percentage on annual worldwide net sales of such licensed product. In addition, we are obligated to pay to Gemma a percentage of sublicensing income, ranging from the mid-single digits to low double digits, for sublicenses under the Gemma Collaboration Agreement. The agreement will expire on a licensed product-by-licensed product and country-by-country basis upon the later of (i) the expiration of the last valid claim of the licensed patent rights that covers the exploitation of such licensed product in such country, and (ii) the expiration of the royalty period. If we were to exercise any of the four options, we would owe Gemma a non-refundable aggregate fee of $1.0 million per product indication, with $0.5 million due upfront and another $0.5 million fee owed upon a further developmental milestone. Gemma - Sublicense Agreements and Transition Services AgreementIn connection with the transfer of the Outlicensed Programs to Gemma, we have entered into the Gemma Sublicenses, pursuant to which, we will receive (i) initial payments of an aggregate of $10.0 million for licenses and clinical product supply; (ii) up to an additional $10.0 million contingent on the completion by Gemma of certain business milestones; (iii) up to an additional $114.0 million in development and commercial milestone payments; and (iv) single digit royalties as a percentage of annual worldwide net sales in exchange for sublicenses to relevant intellectual property, transfer of regulatory dossiers and transfer of clinical trial materials and product supply related to the Outlicensed Programs. In addition, Gemma is responsible for all payments to Penn related to the Outlicensed Programs under the Penn License Agreement. In addition, we entered into a transition services agreement with Gemma pursuant to which (i) we provide transitional services at cost to Gemma for a period of up to six months related to the transfer of the Outlicensed Programs and (ii) Gemma reimburses us for certain costs related to conduct of the Outlicensed Programs incurred since March 1, 2024.Collaboration and Manufacturing and Supply AgreementsCatalentIn June 2019, we entered into a collaboration agreement, or the Collaboration Agreement, with Catalent Maryland, a unit of Catalent, Inc., or Catalent. As part of the Collaboration Agreement, we were required to pay an annual fee for five years ending in 2025 for the exclusive use of a dedicated clean room suite, or the Clean Room Suite. In April 2020, we entered into a development services and clinical supply agreement, or the Manufacturing and Supply Agreement, with Catalent to secure clinical scale manufacturing capacity for batches of active pharmaceutical ingredients for our gene 34Table of Contentstherapy product candidates. Under the terms of the Manufacturing and Supply Agreement, Catalent agreed to manufacture batches of drug product for our gene therapy product candidates at the Clean Room Suite at a Catalent facility provided for in the Collaboration Agreement. The Manufacturing and Supply Agreement provided for a term of five years. The Manufacturing and Supply Agreement also included minimum annual purchase commitments.Under both the Collaboration Agreement and the Manufacturing and Supply Agreement, we had an annual minimum commitment of $10.6 million per year owed to Catalent for five years from November 2020 subject to certain inflationary adjustments.On March 31, 2023, we entered into certain letter agreements, the Letter Agreements, amending each of (i) the Collaboration Agreement and (ii) the Manufacturing and Supply Agreement, together with the Collaboration Agreement, the Original Catalent Agreements. On November 9, 2023, to supersede and implement the terms of the Letter Agreements, we entered into an amended and restated collaboration agreement and an amended and restated manufacturing and supply agreement, together the Amended Catalent Agreements.The Amended Catalent Agreements eliminate the minimum annual purchase obligation and the obligation to pay an annual fee for use of the Clean Room Suite, thereby eliminating the annual minimum commitment of $10.6 million per year owed to Catalent through November 2025 under the Original Catalent Agreements. In consideration of this, we had an obligation to make aggregate payments to Catalent of $6.0 million between June 30, 2023 and May 1, 2024. As of SeptemberÂ 30,Â 2024, we have made all payments related to this obligation under the Amended Catalent Agreements.The Amended Catalent Agreements extend the term of the Original Catalent Agreements until November 6, 2030, and establish a limited

exclusive relationship between us and Catalent for the manufacture of bulk drug substance and drug product for our adeno-associated virus delivery therapeutic product candidates for the treatment of FTD and GM1. The limited exclusive relationship under the Amended Catalent Agreements converts to a non-exclusive relationship (i) in the event Catalent fails to meet certain performance standards and (ii) following certain conditional events related to the divestiture by us of either FTD or GM1, in which case, if such events occur, we would pay Catalent certain fees. The outlicense of GM1 to Gemma under the Outlicense Transaction Agreements, and subsequent business decisions implemented by Gemma in their sole discretion, could be considered an event related to the divesture of GM1 under the Amended Catalent Agreements and require us to make payment of certain fees to Catalent, which fees are immaterial.Immediately prior to the execution of the Letter Agreements, we had a $5.3 million prepaid asset related to upfront payments made to secure the Clean Room Suite. In connection with the Letter Agreements, we no longer have exclusive access to the Clean Room Suite at Catalent and, as a result, we recognized an expense of $5.3 million related to the elimination of the prepaid asset during the nine months ended SeptemberÂ 30,Â 2023. We classified the $11.3 million of expenses, which comprises of $6.0 million in aggregate payments due to Catalent and the $5.3 million elimination of the prepaid asset, as general and administrative expense within the statement of operations for the nine months ended SeptemberÂ 30,Â 2023, as both amounts did not directly relate to the future advancement of our research and development programs.Components of Results of OperationsResearch and DevelopmentResearch and development expenses consist primarily of costs incurred in connection with the development of our product candidates. These expenses include:â—expenses incurred to conduct the necessary preclinical studies and clinical trials required to obtain regulatory approval, including payments to clinical research organizations, or CROs, and payments to GTP and Gemma for preclinical research and development;â—personnel expenses, including salaries, benefits and share-based compensation expense for employees engaged in research and development functions;35Table of Contentsâ—expenses incurred under agreements with contract development and manufacturing organizations, or CDMOs, including the cost of acquiring and manufacturing preclinical study and clinical trial materials;â—expenses and fees paid to consultants who assist with research and development activities; andâ—expenses incurred at and for our lab facilities, including rent, utilities, depreciation, and maintenance.We track outsourced development expenses and other external research and development expenses to specific product candidates on a program-by-program basis, such as fees paid to CROs, CDMOs and research laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities, expenses incurred under our prior collaboration with Penn, and future expenses incurred under the Gemma Collaboration Agreement. However, we do not track our internal research and development expenses on a program-by-program basis as they primarily relate to compensation, lab operations and lab facility costs, and other expenses which are deployed across multiple projects under development.Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development expenses than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. â€‹We expect our research and development expenses to remain consistent in the near future. We expect that the reduction of expenses related to the Outlicensed Programs pursuant to the Outlicense Transaction Agreements will offset the increased expenses of advancing our remaining product candidates in the near future. If our product candidate portfolio progresses into later-stage clinical trials, we expect that our research and development expenses will increase in the future to support our continued research and development activities and production of clinical supply.â€‹General and Administrative ExpensesGeneral and administrative expenses consist primarily of personnel expenses, including salaries, benefits and share-based compensation expense, for employees and consultants in executive, finance, accounting, legal, information technology, product strategy, quality, regulatory, operations and human resource functions. General and administrative expenses also include headquarters facility costs, including rent, utilities, depreciation and maintenance, legal expenses related to intellectual property, litigation and corporate matters, insurance expense, expenses related to contract modifications or terminations, software expenses, expenses incurred to engage with patient advocacy organizations, recruitment related expenses, and expenses for other professional and consulting services. We expect our general and administrative expenses to remain consistent in the near future.If our product candidate portfolio progresses into later-stage clinical trials, we expect that our general and administrative expenses will increase in the future to support our continued research and development activities and potential commercialization efforts. These increases will likely include increased expenses related to the hiring of additional personnel in general and administrative functions, and expenses related to pre-commercialization efforts. If any of our current or future product candidates obtain regulatory approval, we expect that we would incur significantly increased expenses associated with building a commercial sales and marketing team.Impairment of Long-Lived AssetsImpairment of long-lived assets consists of non-cash impairment charges recorded to our assets. We review long-lived assets, such as the right of use assets, or ROU assets, or property and equipment, for impairments when events or changes in circumstances indicate the carrying amount of the assets may not be recoverable. During the nine months ended SeptemberÂ 30,Â 2024, we recognized impairment expenses related to a construction in progress asset, property and equipment, and ROU assets in connection with our leased laboratory space in Hopewell, New Jersey, or the Hopewell Laboratory Space. The impairment expenses represent the proportional allocation of total impairments recognized for the asset groups subject to impairment testing in connection with the Hopewell Laboratory Space.â€‹â€‹36Table of ContentsOther Income (Expense), NetOther income (expense), net consists of interest earned on our cash equivalents and marketable securities, amortization of premium and discount on our marketable securities, and income from subleases. Additionally, in the nine months ended SeptemberÂ 30,Â 2023, we recognized other income related to the sale of certain tax credits.Results of OperationsComparison of the three months ended SeptemberÂ 30,Â 2024 and 2023The following table sets forth our results of operations for the three months ended SeptemberÂ 30,Â 2024 and 2023:â€‹Three months ended â€‹â€‹â€‹â€‹â€‹â€‹â€‹SeptemberÂ 30,Â â€‹â€‹â€‹â€‹(in thousands)Â Â Â Â 2024Â Â Â Â 2023Â Â Â Â ChangeOperating expenses:Â â€‹Â Â Â Â â€‹Â Â Â Â â€‹Â Â Research and developmentâ€‹$ 8,656â€‹$ 15,098â€‹$ (6,442)General and administrativeâ€‹Â 7,251â€‹Â 8,184â€‹Â (933)Impairment of long-lived assetsâ€‹â€‹ 4,795â€‹Â 5,390â€‹â€‹ (595)Loss from operationsâ€‹Â (20,702)â€‹Â (28,672)â€‹Â 7,970Other income (expense), netâ€‹Â 1,362â€‹Â 1,562â€‹Â (200)Net lossâ€‹$ (19,340)â€‹$ (27,110)â€‹$ 7,770â€‹Research and Development ExpensesResearch and development expenses decreased by $6.4 million to $8.7 million for the three months ended SeptemberÂ 30,Â 2024 from $15.1 million for the three months ended SeptemberÂ 30,Â 2023. The decrease was primarily due to the following:â—a decrease of $1.8 million in wages and benefits related to severance costs incurred in the three months ended September 30, 2023;â—a decrease of $1.5 million in clinical operations expenses driven by lower activity in supporting the GM1 and Krabbe programs, partially offset by increased activity for FTD;â—a decrease of $1.3 million in Penn expenses related to the termination of our discovery research obligation under the Penn Agreement;â—a decrease of $0.9 million in share-based compensation expense related to reductions in headcount;â—a decrease of $0.5 million in chemistry, manufacturing and control expenses primarily related to lower external manufacturing expenses, most significantly related to reduced external manufacturing activities for our GM1 program;â—a decrease of $0.3 million in professional fees; andâ—a decrease of $0.2 million in facility and other expenses.â€‹These decreases were partially offset by:â—an increase of $0.1 million for pre-clinical studies to evaluate the efficacy of PBFT02 in models of neurodegenerative disorders.â€‹â€‹37Table of ContentsGeneral and Administrative ExpensesGeneral and administrative expenses decreased by $0.9 million to $7.3 million for the three months ended SeptemberÂ 30,Â 2024 from $8.2 million for the three months ended SeptemberÂ 30,Â 2023. The decrease was primarily due to the following:â—a decrease of $1.2 million in wages and benefits related to severance costs incurred in the three months ended September 30, 2023;â—a decrease of $0.6 million in share-based compensation expense related to reductions in headcount; andâ—a decrease of $0.1 million in facility and other expenses.â€‹These decreases were partially offset by:â€‹â—an increase of $1.0 million in accruals for litigation matters.â€‹Impairment of Long-Lived Assets During the three months ended SeptemberÂ 30,Â 2024, we recorded $4.8 million of impairment expense related to the Hopewell Laboratory Space. The impairment charges consisted of $2.5 million and $2.3 million recorded to the ROU assets and property and equipment, net, respectively. During the three months ended SeptemberÂ 30,Â 2023, we recorded $5.4 million of impairment expense in connection with Sublease Agreement A and Sublease Agreement B. The impairment charges consisted of $2.2 million and $3.2 million recorded to the ROU assets and property and equipment, net, respectively. Other Income (Expense), NetOther income (expense), net decreased by $0.2 million to $1.4 million for the three months ended SeptemberÂ 30,Â 2024 from $1.6 million for the three months ended SeptemberÂ 30,Â 2023. The decrease was primarily due to the following: â—a decrease of $0.5 million attributable to interest income and the amortization of premium and discount on our marketable securities.â€‹The decrease was partially offset by:â—an increase of $0.3 million attributable to income from subleases.â€‹Comparison of the nine months ended SeptemberÂ 30,Â 2024 and 2023â€‹The following table sets forth our results of operations for the nine months ended SeptemberÂ 30,Â 2024 and 2023:â€‹Nine months ended â€‹â€‹â€‹â€‹â€‹â€‹â€‹SeptemberÂ 30,Â â€‹â€‹â€‹â€‹(in thousands)Â Â Â Â 2024Â Â Â Â 2023Â Â Â Â ChangeOperating expenses:Â â€‹Â Â Â Â â€‹Â Â Â Â â€‹Â Â Research and developmentâ€‹$ 30,621â€‹$ 49,258â€‹$ (18,637)General and administrativeâ€‹Â 20,276â€‹Â 35,295â€‹Â (15,019)Impairment of long-lived assetsâ€‹â€‹ 5,233â€‹Â 5,390â€‹â€‹ (157)Loss from operationsâ€‹Â (56,130)â€‹Â (89,943)â€‹Â 33,813Other income (expense), netâ€‹Â 4,088â€‹Â 4,639â€‹Â (551)Net lossâ€‹$ (52,042)â€‹$ (85,304)â€‹$ 33,262â€‹â€‹38Table of ContentsResearch and Development ExpensesResearch and development expenses decreased by $18.7 million to $30.6 million for the nine months ended SeptemberÂ 30,Â 2024 from $49.3 million for the nine months ended SeptemberÂ 30,Â 2023. The decrease was primarily due to the following:â—a decrease of $4.4 million in wages and benefits related to reductions in headcount;â—a decrease of $4.1 million in Penn expenses related to the pausing of certain programs in our preclinical portfolio, reduction of post-IND support for our clinical stage programs, and termination of our discovery research obligation under the Penn Agreement;â—a decrease of $4.0 million in clinical operations expenses driven by lower activity in supporting the GM1 and Krabbe programs, partially offset by increased activity for FTD;â—a decrease of $2.7 million in share-based compensation expense related to reductions in headcount;â—a decrease of $2.1 million in chemistry, manufacturing and control expenses primarily related to lower external manufacturing expenses, most significantly related to (i) reduced external manufacturing activities for our GM1 program and (ii) reduced expenses for Clean Room Suite fees related to the Amended Catalent Agreements;â—a decrease of $1.1 million in professional fees; andâ—a decrease of $0.6 million in facility and other expenses.â€‹These decreases were partially offset by:â—an increase of $0.3 million for pre-clinical studies to evaluate the efficacy of PBFT02 in models of neurodegenerative disorders.â€‹General and Administrative ExpensesGeneral and administrative expenses decreased by $15.0 million to $20.3 million for the nine months ended SeptemberÂ 30,Â 2024 from $35.3 million for the nine months ended SeptemberÂ 30,Â 2023. The decrease was primarily due to the following:â—a decrease of $11.3 million related to expenses incurred in conjunction with the Amended Catalent Agreements during the nine months ended SeptemberÂ 30,Â 2023;â—a decrease of $2.8 million in wages and benefits related to reductions in headcount;â—a decrease of $2.1 million in share-based compensation expense related to reductions in headcount; andâ—a decrease of $0.5 million in facility and other expenses.â€‹These decreases were partially offset by:â—an increase of $1.0 million in accruals for litigation matters, andâ—an increase of $0.7 million for professional services and consulting.â€‹Impairment of Long-Lived Assets During the nine months ended SeptemberÂ 30,Â 2024, we recorded $5.2 million of impairment expense primarily consisting of $2.5 million and $2.3 million recorded to the ROU assets and property and equipment, net, respectively, related to the Hopewell Laboratory Space. In addition, we recorded $0.4 million of impairment expenses related to property and equipment for a construction in progress asset we no longer plan to deploy.39Table of ContentsDuring the nine months ended SeptemberÂ 30,Â 2023, we recorded $5.4 million of impairment expense in connection with Sublease Agreement A and Sublease Agreement B. The impairment charges consisted of $2.2 million and $3.2 million recorded to the ROU assets and property and equipment, net, respectively.Other Income (Expense), NetOther income (expense), net decreased by $0.5 million to $4.1 million for the nine months ended SeptemberÂ 30,Â 2024 from $4.6 million for the nine months ended SeptemberÂ 30,Â 2023. The decrease was primarily due to the following: â—a decrease of $0.6 million attributable to interest income and the amortization of premium and discount on our marketable securities; andâ—a decrease of $0.5 million attributable to the sale of certain tax credits during the nine months ended SeptemberÂ 30,Â 2023.â€‹These decreases were partially offset by:â—an increase of $0.6 million attributable to income from subleases.â€‹Liquidity and Capital ResourcesOverviewAs of SeptemberÂ 30,Â 2024, we had $84.8Â million in cash, cash equivalents and marketable securities and had an accumulated deficit of $646.5 million. We expect our existing cash, cash equivalents and marketable securities, combined with the remaining initial payments for the licenses and clinical product supply in connection with the Gemma Sublicenses and expected payments in connection with the Transition Services Agreement, will enable us to fund our operating expenses and capital expenditure requirements to the end of the second quarter of 2026.Funding RequirementsOur primary use of cash is to fund operating expenses, most significantly research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:â—the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;â—the expenses of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;â—the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;â—the expenses of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;â—the expenses and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;40Table of Contentsâ—the expenses related to general and administrative functions to support our product candidates;â—our ability to establish additional collaborations on favorable terms, if at all;â—the expenses required to scale up our clinical, regulatory and manufacturing capabilities;â—the expenses of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; andâ—revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholdersâ€™ ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholdersâ€™ rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, further reduce or terminate our research, product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.On March 5, 2021, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, relating to the applicable terms of at-the-market equity offerings, or the ATM Facility, pursuant to which we may, but are not obligated to, offer and sell, from time to time, shares of our common stock with an aggregate offering price up to $125.0 million through Cowen, as sales agent in the ATM Facility. We issued 6,000,000 shares of common stock under the ATM Facility, resulting in net proceeds of $8.7 million, after deducting offering costs of $0.3 million in March 2024. We are limited to $50.0 million in our capacity to offer and sell shares of our common stock under this sales agreement pursuant to our shelf registration statement on Form S-3, filed on March 4, 2024. As of SeptemberÂ 30,Â 2024, $50.0 million of capacity remains available to be sold under the ATM Facility.Cash FlowsThe following table shows a summary of our cash flows for the periods indicated:â€‹Nine months ended â€‹â€‹SeptemberÂ 30,Â (in thousands)â€‹â€‹2024â€‹2023Cash provided by (used in) operating activitiesÂ Â Â Â $ (39,512)Â Â Â Â $ (58,748)Cash provided by (used in) investing activitiesâ€‹Â 41,268â€‹Â 57,637Cash provided by (used in) financing activitiesâ€‹Â 8,827â€‹Â 89Net increase (decrease) in cash and cash equivalentsâ€‹â€‹ 10,583â€‹$ (1,022)41Table of ContentsNet Cash Provided by (Used in) Operating ActivitiesDuring the nine months ended SeptemberÂ 30,Â 2024, we used $39.5 million of net cash in operating activities. Cash used in operating activities reflected a net loss of $52.0Â million, partially offset by a net decrease in our operating assets of $1.5 million, and net non-cash charges of $11.0 million related to depreciation, amortization, share-based compensation, amortization of premium and discount, net, and

impairment of long-lived assets. The primary use of cash was to fund our operations related to the development of our product candidates.During the nine months ended SeptemberÂ 30,Â 2023, we used $58.7 million of net cash in operating activities. Cash used in operating activities reflected a net loss of $85.3 million, partially offset by a net decrease in our operating assets of $9.6 million and net non-cash charges of $17.0 million primarily related to share-based compensation, depreciation, amortization, impairment of long-lived assets, and amortization of premium and discount, net. The primary use of cash was to fund our operations related to the development of our product candidates.Net Cash Provided by (Used in) Investing ActivitiesDuring the nine months ended SeptemberÂ 30,Â 2024, we purchased $72.6 million in marketable securities, and had sales and maturities of $113.9 million in marketable securities. Purchases of property and equipment were de minimus for the nine months ended SeptemberÂ 30,Â 2024.During the nine months ended SeptemberÂ 30,Â 2023, we purchased $101.6 million in marketable securities, and had sales and maturities of $159.4 million in marketable securities. Purchases of property and equipment were $0.1 million for the nine months ended September 30, 2023.Net Cash Provided by (Used in) Financing ActivitiesDuring the nine months ended SeptemberÂ 30,Â 2024, we received $8.7 million in net proceeds from the issuance of common stock under the ATM Facility. We received gross proceeds of $9.0 million, net of offering costs of $0.3 million. We received $0.1 million in proceeds from the issuance of common stock under the ESPP and exercises of employee stock options.During the nine months ended SeptemberÂ 30,Â 2023, we received $0.1 million in proceeds from the issuance of common stock under the ESPP.Contractual Obligations and Other Commitmentsâ€‹We lease approximately 37,000 square feet of office space in Philadelphia, Pennsylvania, or the 2005 Market Street Lease Agreement. The lease will expire in December 2031. We have an option to extend the term of the lease by up to two additional five-year terms. The aggregate estimated rent payments due over the initial term of the lease is $11.8 million, with rent payments that began in 2022. Our sublease agreements do not relieve us from our primary obligations under the 2005 Market Street Lease Agreement, however, we do expect cash inflows from the agreements to partially offset our future obligations for the duration of the sublease agreements.â€‹We sublease approximately 16,000 square feet of office space in Philadelphia, Pennsylvania, or the 1835 Market Street Sublease Agreement. The sublease will expire in August 2025. We have an option to extend the term of the sublease by three and a half years through February 2029. The aggregate estimated rent payments due over the initial term of the sublease is approximately $0.5 million, with rent payments that began in 2024.â€‹We lease approximately 62,000 square feet of laboratory space in Hopewell, New Jersey, or the Laboratory Lease Agreement. The lease will expire in March 2036. The aggregate estimated rent payments due over the initial term of the lease is approximately $40.3 million, with rent payments that began in 2021. Our sublease agreement does not relieve us from our primary obligations under the Laboratory Lease Agreement, however, we do expect cash inflows from the agreement to partially offset our future obligations for the duration of the sublease agreement.â€‹42Table of ContentsUnder the exclusive relationship under the Amended Catalent Agreements, following certain conditional events related to the divestiture by us of either FTD or GM1, we would pay Catalent certain fees. The outlicense of GM1 to Gemma under the Outlicense Transaction Agreements, and subsequent business decisions implemented by Gemma in their sole discretion, could be considered an event related to the divesture of GM1 under the Amended Catalent Agreements and require us to make payment of certain fees to Catalent, which fees are immaterial.â€‹Under the Penn Agreement, we agreed to fund discovery research conducted by GTP for five years, which began in May 2020. Our funding commitment was $5.0 million annually through June 2026. As a result of the Outlicense Transaction Agreements, we have amended the Penn Agreement to eliminate this commitment as of July 31, 2024. No discovery research funding commitments exist under the Gemma Collaboration Agreement.â€‹These contractual obligations and commitments are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. Payments due upon cancellation consisting only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation are not included as the amount and timing of such payments are not known.â€‹The contractual obligations and commitments above do not include any potential milestone or royalty payments that we may be required to make under the Penn License Agreement. Under the Gemma Sublicenses, Gemma will be responsible for all potential milestone and royalty payments to Penn for the Outlicensed Programs.â€‹Critical Accounting Policies and EstimatesDuring the nine months ended SeptemberÂ 30,Â 2024, there were no material changes to our critical accounting policies and estimates from those described under the heading â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€”Critical Accounting Policies and Estimatesâ€ in our 2023 Annual Report filed on Form 10-K, except for those described below.License and Other RevenueWe may enter into license agreements and transition services agreements under which we may license rights to research, develop, manufacture, and commercialize our product candidates to third parties, and provide transition services for such licenses. Payments under these arrangements may include non-refundable, upfront fees, reimbursement of certain costs, payments upon the achievement of certain milestones, and royalties on product sales. We apply ASC Topic 606,â€¯Revenue from Contracts with Customers, or ASCâ€¯606, when all of the following criteria are met, to determine a valid contract exists: (i) the parties have approved the contract and are committed to perform their respective obligations; (ii) we can identify each partyâ€™s rights regarding the goods or services to be transferred; (iii) we can identify the payment terms for the goods or services to be transferred; (iv) the contract has commercial substance; and (v) we will collect substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer. Once it is determined that a valid contract exists, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including consideration of the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations on a relative stand-alone selling price basis; and (v) recognition of revenue when (or as) we satisfy each performance obligation. As part of the accounting for these arrangements, we must use our judgment to determine the number of performance obligations, the transaction price, the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price, the contract term and pattern of satisfaction of the performance obligations. We use judgment to determine whether milestones or other variable consideration, except for certain sales-based milestone payments and royalties, should be included in the transaction price as described further below.At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most 43Table of Contentslikely amount method set forth in ASC 606. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee, such as those subject to regulatory approvals, are not considered probable of being achieved until those approvals are received. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the statements of operations in the period of adjustment. For customer contracts in the scope of ASC 606, amounts due to us are recorded as accounts receivable on our balance sheet when our right to consideration is unconditional. Amounts received prior to satisfying the related performance obligations are classified on our balance sheet as current deferred revenue if expected to be recognized as revenue within 12 months following the balance sheet date and as deferred revenue, net of current portion, if amounts are not expected to be recognized as revenue within the 12 months following the balance sheet date. We do not evaluate a contract for a significant financing component if payment is expected within one year or less from the transfer of promised items to the customer.JOBS Act Accounting ElectionWe are an â€œemerging growth companyâ€ as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.We will remain an emerging growth company until the earliest of (1) the last day of our first fiscal year (a) in which we have total annual gross revenues of at least $1.235 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, (2) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period and (3) December 31, 2025.We are also a â€œsmaller reporting company,â€ meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.Recent Accounting PronouncementsSee NoteÂ 3 to our unaudited interim financial statements included elsewhere in this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.44Table of ContentsItemÂ 3. Quantitative and Qualitative Disclosures About Market Risk.Not applicable.â€‹ItemÂ 4. Controls and Procedures.Evaluation of Disclosure Controls and ProceduresAs of SeptemberÂ 30,Â 2024, management, with the participation of our Principal Executive Officer and Principal Financial and Accounting Officer, performed an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SECâ€™s rules and forms, and that such information is accumulated and communicated to our management, including the Principal Executive Officer and Principal Financial and Accounting Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Principal Executive Officer and Principal Financial and Accounting Officer concluded that, as of SeptemberÂ 30,Â 2024, our disclosure controls and procedures were effective at a reasonable assurance level.Changes in Internal Control Over Financial ReportingThere were no changes in our internal control over financial reporting that occurred during the quarter ended SeptemberÂ 30,Â 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.â€‹45Table of ContentsPARTÂ II-OTHER INFORMATIONItemÂ 1. Legal ProceedingsFrom time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are currently a defendant in litigation with a former employee in the Court of Common Pleas of Philadelphia County (Commerce Division), or the Court, relating to a claim of breach of contract and violation of the Pennsylvania Wage Payment and Collection Law, or the Claim. The plaintiff claims that, pursuant to an alleged settlement agreement reached on February 3, 2020, we agreed to issue plaintiff 150,000 shares of its common stock and that such shares would not be subject to the reverse stock split implemented by us in connection with our initial public offering on February 14, 2020. The plaintiffâ€™s claim is for an amount in the mid-single digit millions of dollars. We disagree with the allegations that there was ever a binding settlement agreement or that any shares would not be subject to the reverse stock split. In October 2023, the Court denied both our and the plaintiffâ€™s motions for summary judgement and a trial date was set for October 2024. We have vigorously defended against these claims. On October 28, 2024, the Court entered a directed verdict in favor of the Company on the Pennsylvania Wage Payment and Collection Claim, and on October 29, the jury found for the plaintiff in the amount of $1.0 million on the breach of contract Claim, which we have accrued for and recognized in general and administrative expenses for the three and nine months ended September 30, 2024. The jury verdict is subject to post-trial motions and we will consider whether to appeal if our motions are denied and judgment is entered on the verdict.Other than the above, we are not presently a party to any legal proceedings that, in the opinion of management, would, if decided against us, have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.Item 1A. Risk Factors.Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks and uncertainties described below, together with the other information contained in this quarterly report, including our financial statements and the related notes and â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operations.â€ The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.Summary of Risk FactorsOur business is subject to a number of risks and uncertainties, including those immediately following this summary. Some of these risks are:â€‹â—We are a clinical stage genetic medicines company with a history of operating losses, and we may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. Our limited operating history may make it difficult for you to evaluate our success to date and to assess our future viability;â€‹â—We will need to raise additional funding before we can expect to become profitable from any potential future sales of our products;â€‹â—PBFT02 is currently our sole clinical stage product candidate and we may not be able to successfully develop and commercialize PBFT02;â€‹46Table of Contentsâ—We are early in our development efforts. Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them;â€‹â—Certain disorders we seek to treat have low incidence and prevalence and it may be difficult to identify patients with these diseases, which may lead to delays in enrollment for our trials or slower commercial revenue if approved;â€‹â—Preclinical and clinical development involve lengthy and expensive processes with uncertain outcomes. We may incur additional expenses or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates;â€‹â—Gene therapy is a novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval;â€‹â—Our product candidates may cause undesirable and unforeseen side effects, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences;â€‹â—We currently rely on our collaboration with Gemma for many aspects of our preclinical research and development programs, including for discovering, preclinically developing and conducting IND-enabling studies for our preclinical product candidates and our near-term future pipeline of product candidates;â€‹â—Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business;â€‹â—We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies or technologies that are more advanced or effective than ours;â€‹â—We currently rely and expect to continue to rely on third-party manufacturers to produce clinical supply of our product candidates; â€‹â—Even if we are able to obtain regulatory approval for and commercialize our product candidates, our products may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business; â€‹â—The price of our common stock does not meet the requirements for continued listing on The Nasdaq Global Select Market. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting; andâ€‹â—If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under licensed patents is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.â€‹â€‹47Table of ContentsRisks Related to Our Financial Position and Need for Additional Capitalâ€‹We are a clinical stage genetic medicines company with a history of operating losses, and we may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.â€‹We are a clinical stage genetic medicines company with a limited operating history on which to base your investment decision. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of

risk. Our operations to date have been limited primarily to staffing our company, business planning, raising capital, entering into collaboration and vendor agreements for conducting preclinical research and clinical development activities for our product candidates, and performing clinical development activities and manufacturing clinical supply. All of our product candidates are in the clinical development stage, have been outlicensed to a third party, or are in the preclinical or discovery stage. We have no products approved for commercial sale and have not generated any revenue from commercial product sales, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. We have generally funded our operations to date through proceeds from sales of our convertible preferred stock, and public offerings, and do not expect to receive revenue from commercial product sales, for many years, if ever.We have incurred net losses since our inception in 2017. We incurred net losses of $52.0 million and $85.3 million for the nine months ended SeptemberÂ 30,Â 2024 and 2023, respectively. As of SeptemberÂ 30,Â 2024, we had an accumulated deficit of $646.5 million. Substantially all of our operating losses have resulted from expenses incurred in connection with our research and development programs, acquiring the rights to our product candidates, and from general and administrative expenses associated with our operations. We expect to continue to incur significant expenses and operating losses over the next severalÂ years and for the foreseeable future as we intend to continue to conduct research and development, clinical testing, regulatory compliance activities, manufacturing activities, and, if any of our product candidates is approved, sales and marketing activities that, together with anticipated general and administrative expenses, will likely result in us incurring significant losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholdersâ€™ equity and working capital.We expect that it will be severalÂ years, if ever, before we have a commercialized product. We anticipate that our expenses will increase substantially if, and as, we:â€¢advance our product candidates from the preclinical or discovery stage to the clinical development stage;â€¢advance our clinical product candidates into later stage clinical development;â€¢seek regulatory approvals for any product candidates that successfully complete clinical trials;â€¢hire additional clinical, quality control, regulatory, manufacturing, scientific and administrative personnel;â€¢expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;â€¢expand or build our internal manufacturing capabilities;â€¢maintain, expand and protect our intellectual property portfolio; andâ€¢incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.We have never generated revenue from product sales and may never achieve or maintain profitability.â€‹We have no products approved for commercial sale and have not generated any revenue from commercial product sales. To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential, which will require us to be successful in a range of challenging activities. These activities can include completing preclinical studies and initiating and completing clinical trials of our product candidates, obtaining marketing 48Table of Contentsapproval for these product candidates, manufacturing, obtaining coverage and adequate reimbursement from government and third-party payors, marketing, distributing, and selling those products that are approved and satisfying any post marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability.Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.We will need to raise additional funding before we can expect to become profitable from any potential future sales of our products. This additional financing may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit, or terminate our product development efforts or other operations.â€‹We will require substantial future capital in order to complete planned and future preclinical and clinical development for our portfolio of product candidates and potentially commercialize these product candidates, if approved. If our product portfolio progresses into later stage clinical trials, or our current preclinical product candidates progress into the clinical trial stage, we expect our spending levels to significantly increase in connection with our continued clinical trial activities and production of our clinical product candidatesâ€™ supply. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant expenses related to product sales, medical affairs, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Our ability to raise additional funds also depends on general financial, economic and market conditions as well as other factors, including financial institutions that may experience insolvency or financial distress similar to that experienced by both Silicon Valley Bank and Signature Bank in March 2023, over which we may have no or limited control. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate certain of our licensing activities, our research and development programs or other operations.Our operations have consumed significant amounts of cash since inception. As of SeptemberÂ 30,Â 2024, our cash, cash equivalents and marketable securities were $84.8 million. We expect that our existing cash, cash equivalents and marketable securities, combined with the remaining initial payments from the Gemma Sublicenses and expected payments in connection with the Transition Services Agreement, will enable us to fund our operating expenses and capital expenditure requirements to the end of the second quarter of 2026. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:â—the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;â—the expenses of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;â—the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;â—the expenses of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;â—the expenses and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;â—our ability to establish collaborations on favorable terms, if at all;â—the expenses required to scale up our clinical, regulatory and manufacturing capabilities;49Table of Contentsâ—the expenses of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval;â—the availability of coverage and adequate reimbursement from government and third-party payors for our product candidates for which we receive marketing approval; andâ—revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.â€‹Accordingly, we will need to continue to rely on additional financing to achieve our business objectives, which may not be available to us on acceptable terms, or at all. For example, we are party to the Sales Agreement with Cowen relating to the sale and issuance, from time to time, shares of our common stock in at-the-market equity offerings with an aggregate offering price up to $125.0 million, or the ATM Facility. $9.0 million of shares of our common stock have been sold under the ATM Facility as of SeptemberÂ 30,Â 2024.We may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis or on terms acceptable to us, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more product candidates or discovery stage programs or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidates, if approved.Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.â€‹Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or securities convertible into equity, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures or declaring dividends.If we raise additional funds through collaborations, strategic alliances or marketing, distribution 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 financings when needed or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.Risks Related to Product Development and Regulatory Approvalâ€‹PBFT02 is currently our sole clinical stage product candidate and we may not be able to successfully develop and commercialize PBFT02.We are currently dependent on the potential development of a single clinical product candidate, PBFT02. We are still developing our sole clinical product candidate, and PBFT02 cannot be marketed or sold in the United States or in foreign markets until regulatory approval has been obtained from the FDA or applicable foreign regulatory agencies. The process of obtaining regulatory approval is expensive and time consuming. The FDA and foreign regulatory authorities may never approve PBFT02 for sale and marketing, and even if PBFT02 is ultimately approved, regulatory approval may be delayed or limited in the United States or in other jurisdictions. Even if we are authorized to sell and market PBFT02 in one or more markets, there is no assurance that we will be able to successfully market PBFT02 or that PBFT02 will achieve market acceptance sufficient to generate profits. If we are unable to successfully develop and commercialize PBFT02 due to failure to obtain regulatory approval for PBFT02, to successfully market PBFT02 or, to 50Table of Contentsgenerate profits from the sale of PBFT02 due to other risk factors outlined in this report, it would have material adverse effects on our business, financial condition, and results of operations.We are early in our development efforts. Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them. If we are unable, or experience significant delays in doing so, our business will be materially harmed.â€‹We are early in our clinical development efforts and our clinical product candidates are in early phase clinical trials. Additionally, we have a portfolio of programs that are in different stages of preclinical development and some may never advance to clinical stage development. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We currently generate no revenue from sales of any product and we may never be able to develop or commercialize a marketable product.Each of our programs and product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the FDA, or certain other ex-U.S. regulatory agencies before we may commercialize our product candidates.The clinical and commercial success of our product candidates will depend on several factors, including the following:â—timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies, biocompatibility studies and minimally efficacious dose studies in animals, where applicable;â—effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;â—successful enrollment and completion of clinical trials, including under the international current Good Clinical Practices, or cGCPs, and current Good Laboratory Practices, or GLPs;â—positive results from our current and future clinical programs that support a finding of safety and effectiveness and an acceptable benefit-risk profile of our product candidates in the intended populations;â—receipt of marketing approvals from applicable regulatory authorities;â—establishment of arrangements with third-party manufacturers or our own facilities for clinical supply and, where applicable, commercial manufacturing capabilities;â—establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;â—commercial launch of our product candidates, if approved, whether alone or in collaboration with others;â—acceptance of the benefits and use of our product candidates, including method of administration, if and when approved, by patients, the medical community and third-party payors;â—effective competition with other therapies;â—establishment and maintenance of healthcare coverage and adequate reimbursement and patientsâ€™ willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;â—establishment of a physician training system and network for administration of our product candidates by administration into the ICM;â—enforcement and defense of intellectual property rights and claims; andâ—maintenance of a continued acceptable safety, tolerability and efficacy profile of our product candidates following approval.â€‹If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we are unable to advance our product candidates to clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.51Table of ContentsPreclinical and clinical development involve lengthy and expensive processes with uncertain outcomes. We may incur additional expenses or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.â€‹All of our product candidates are in clinical or preclinical development and their risk of failure is high. We also rely on third-parties, such as Gemma, for our preclinical and IND-enabling studies. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. We will rely on contract laboratories and other third parties, or our CROs, for the clinical development of our clinical product candidates. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials or early cohorts of our clinical trials of our product candidates, including early biomarker data, may not be predictive of the results of later-stage clinical trials or later cohorts of our clinical trials. Early clinical trials and in particular initial cohorts of early clinical trials often enroll significantly fewer patients than later stage clinical trials or later cohorts of the same clinical trial and may not be as predictive as larger trials. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful or come to agreement on other aspects of clinical trial design. Moreover, a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support clinical development of our current or any of our future product candidates.We, or our collaborators, may experience delays in initiating or completing clinical trials. We, or our collaborators, also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our clinical product candidates or any future product candidates, including:â—regulators, such as the FDA, may place our clinical trials on clinical hold;â—institutional review boards, or IRBs, the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;â—delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective CROs the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;â—clinical trial sites deviating from trial protocol or dropping out of a trial;â—novel therapies, such as gene therapies with less well-characterized safety profiles, may require slower or more staggered early clinical trial enrollment to adequately assess safety data;â—clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;â—the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow up at a higher rate than we anticipate;â—our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which

may require that we add new clinical trial sites or investigators;â—we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;52Table of Contentsâ—expenses of clinical trials of any of our product candidates may be greater than we anticipate;â—the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;â—our inability to manufacture sufficient quantities of our product candidates for use in clinical trials;â—reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;â—our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as our product candidate; andâ—the FDA or ex-U.S. regulatory agencies may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.â€‹Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including: the size and nature of the patient population; the number and location of clinical sites we enroll; the proximity of patients to clinical sites; the eligibility and exclusion criteria for the trial; the design of the clinical trial; the inability to obtain and maintain patient consents; the risk that enrolled participants will drop out before completion; and competing clinical trials and cliniciansâ€™ and patientsâ€™ perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. For example, treating physicians with eligible patients for our upliFT-D trial may instead elect to use alternative treatment approaches from our competitors, if such competitors are to receive regulatory approval in advance of our program, in lieu of enrolling in our clinical trial.â€‹We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Independent Data Monitoring Committee for such trial. A suspension or termination may be imposed due to a number of factors, including: failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit from using a product or treatment; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.Our product development expenses will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.Success in early preclinical studies or clinical trials may not be indicative of results obtained in later preclinical studies and clinical trials.â€‹Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may 53Table of Contentscause us to incur additional operating expenses. We may experience unexpected or adverse results in our ongoing or future clinical trials. We will be required to demonstrate through adequately designed and executed clinical trials that our product candidates are safe and effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Our current clinical trial for PBFT02 in FTD-GRN patients has relatively small cohorts and results experienced to date may not be indicative of future success. If safety issues arise, we may be delayed or prevented from expanding into subsequent phases of our trial. Earlier gene therapy clinical trials conducted by others also utilized AAV vectors. However, these studies should not be relied upon as evidence that our planned clinical trials will succeed. Trial designs and results from previous trials are not necessarily predictive of our future clinical trial designs or results, and initial positive results we may observe may not be confirmed upon full analysis of the complete trial data. In addition, the positive results we have observed for our product candidates in preclinical animal models may not be predictive of our future clinical trials in humans. Our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development even if they successfully advance through initial clinical trials.Preliminary, topline or interim data from our clinical trials that we or our partners announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.â€‹From time to time, we have made, and may continue to make, public preliminary, topline or interim data from our clinical trials, including preliminary biomarker data. Preliminary or topline data from clinical trials remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data that were previously made public. Interim data from clinical trials that we may complete are also subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. As a result, preliminary, topline and interim data should be viewed with caution until the final data are available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our reputation and business prospects.If we do not achieve our projected development goals in the time-frames we announce and expect, the commercialization of our products may be delayed.â€‹From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials, the release of data from such studies and the submission of regulatory filings, including IND submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.Gene therapy is a novel technology, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Currently, only a limited number of gene therapy products have been approved in the United States and in foreign countries.â€‹Our current product candidates are based on gene therapy technology and our future success depends on the successful development of this novel therapeutic approach. The regulatory requirements that govern any novel gene therapy product candidates we develop are not entirely clear and are subject to change. The clinical study requirements of the FDA and ex-U.S. regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours may be more expensive and take longer than for other, better known or extensively studied product candidates. Further, as we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, only a limited number of gene therapy products have been approved in the United States and foreign countries, 54Table of Contentswhich makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States or other jurisdictions. Further, approvals by ex-U.S. regulatory agency may not be indicative of what the FDA may require for approval, or vice versa.Our product candidates may cause undesirable and unforeseen side effects, which could delay or prevent their advancement into clinical trials or regulatory approval, limit the commercial potential or result in significant negative consequences.â€‹While new AAV vectors have been developed to reduce side effects previously reported in third-party gene therapy treatments, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material.For example, Patient 1 in our upliFT-D trial, who received a low level of immunosuppression (60 mg oral prednisone daily for 60 days) experienced two serious adverse events that were both asymptomatic and likely consistent with an immune response. Subsequently, we amended the protocol to increase the steroid regimen. Additional possible adverse side effects could occur that may substantially limit the effectiveness of the treatment. For example, in previous third-party clinical trials involving AAV vectors for gene therapy, some subjects experienced the development of a T-cell immune response, whereby after the vector is within the target cells, the cellular immune response system triggers the removal of transduced cells by activated T-cells. Other recent clinical trials involving high doses of AAV vectors have also resulted in liver damage and death. Further, following administration of any AAV vector, patients are likely to develop neutralizing antibodies specific to the vector administered. Other preclinical studies have suggested that high dosages of AAV administration may result in toxicity due to degeneration of the dorsal root ganglia. Preliminary results of our NHP toxicology studies for our PBFT02 product candidate have demonstrated trigeminal ganglia and dorsal root ganglia toxicity. Based on these results, and if our vectors demonstrate a similar effect in other programs, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates.In addition to side effects caused by the product candidate, the administration process or related procedures also can cause adverse side effects. Each of our clinical product candidates are expected to utilize ICM administration. While this method of administration has been available for decades, its use for therapies is relatively new, no therapies are currently approved using ICM administration, and it may be perceived as having greater risk than more common methods of administration, such as intravenous injection. If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug or administration process or related procedures, the FDA or ex-U.S. regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.Additionally, if any of our product candidates receives marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategies, or REMS, to ensure that the benefits of the product outweigh its risks, which may include, among other things, a Medication Guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our product candidate, several potentially significant negative consequences could result, including:â—regulatory authorities may suspend or withdraw approvals of such product candidate;â—regulatory authorities may require additional warnings in the labeling;â—we may be required to change the way a product candidate is administered or conduct additional clinical trials;â—we could be sued and held liable for harm caused to patients; and55Table of Contentsâ—our reputation may suffer.â€‹Any of these occurrences may harm our business, financial condition and prospects significantly.Adverse public perception of genetic medicines may negatively impact regulatory approval of, and/or demand for, our potential products.â€‹Regulatory approval of and/or demand for our potential products will depend in part on public acceptance of the use of genetic medicine for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genetic medicines are unsafe, unethical or immoral, and consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, their patients being willing to receive, and third-party payors being willing to cover and reimburse for treatments that involve the use of product candidates we may develop.There have been several significant adverse side effects reported in genetic medicine treatments in the past. For example, in 1999, there was public backlash against gene therapy following the death of a clinical trial subject in a gene therapy clinical trial that utilized an adenovirus vector. It was later discovered that adenoviruses could generate an extreme immune system reaction that can be life threatening. Dr.Â Wilson, who also serves as a consultant to the Company as a Scientific Advisor, was a co-investigator of the 1999 trial while he was Director of the Institute for Human Gene Therapy of Penn. Serious adverse events in our clinical trials, or other clinical trials involving gene therapy by us or our competitors, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception and potential regulatory delays in the clinical testing or approval of our product candidates.As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs.â€‹The design and implementation of clinical trials is a complex process. As an organization, we have limited experience designing and implementing clinical trials, and we may not successfully or cost effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the related expenses to implement the clinical trial, which could lead to a shortfall in funding.Certain disorders we seek to treat have low incidence and prevalence, and it may be difficult to identify patients with these disorders, which may lead to delays in enrollment for our trials or slower commercial revenue if approved.â€‹Genetically defined disorders generally, and especially those for which certain of our current product candidates are targeted, have low incidence and prevalence. For example, we estimate the prevalence of FTD-GRN deficiency in the United States and Europe is approximately 18,000. This could be a significant obstacle to the timely recruitment and enrollment of a sufficient number of eligible patients into our trial. Further, we expect to rely in part on our relationships with patient advocacy groups to assist in identifying eligible patients, and any deterioration of those relationships could impede our ability to successfully enroll patients. Patient enrollment may be affected by other factors including:â—the severity of the disease under investigation;â—design of the study protocol;â—the eligibility criteria for the trial;â—the perceived risks, benefits and convenience of administration of the product candidate being studied;â—our efforts to facilitate timely enrollment in clinical trials;56Table of Contentsâ—the availability of other clinical trials being conducted for the same indication;â—the patient referral practices of physicians; andâ—the proximity and availability of clinical trial sites to prospective patients.â€‹Our inability to enroll a sufficient number of patients with these diseases for our planned clinical trials, including FTD-GRN, would result in significant delays and could require us to not initiate or abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.Additionally, our projections of the number of people who have these disorders, including FTD-GRN, are based on estimates, including third-party analyses commissioned by us. The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, the final approved product labeling for each of our product candidates, if our product candidates are approved for sale in our target indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients globally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Our products may potentially be dosed on a one-time basis, which means that patients who enroll in our clinical trials may not be eligible to receive our products on a commercial basis if they are approved, leading to lower revenue potential.Even if we complete the necessary clinical trials, we cannot predict when, or if, we will receive regulatory approval to commercialize a product candidate and the approval may be for a more narrow indication than we seek.â€‹Prior to commercialization, our product candidates

must be approved by the FDA pursuant to a Biologics License Application, or BLA, in the United States and by similar ex-U.S. regulatory authorities. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes manyÂ years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. Our company does not have experience in submitting and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidateâ€™s safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate.Approval of our product candidates may be delayed or refused for many reasons, including the following:â—the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials, including the methods for collecting and analyzing data, the statistical analysis plan, and the lack of a concurrent control arm or a decision to use external or historical controls;â—the FDA or comparable foreign regulatory authorities may not agree that the efficacy endpoints used in our clinical trials are appropriate to establish clinical benefit in the intended populations;â—we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;â—development of products for ultra rare diseases may involve the use of natural history data as an external control. We may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that the control arm(s) are adequate to establish the safety and/or effectiveness of our product candidates;57Table of Contentsâ—the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;â—we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities a durable response to our product candidates;â—we may be unable to demonstrate that our product candidatesâ€™ clinical and other benefits outweigh their safety risks;â—the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical programs or clinical trials;â—the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;â—the facilities of the third-party manufacturers with which we contract may not be adequate to support approval of our product candidates;â—the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; andâ—even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.â€‹In addition, three decisions from the U.S. Supreme Court in July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agenciesâ€™ interpretations of ambiguous statutory language. The second decision overturned regulatory agenciesâ€™ ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, is unknown. We also cannot predict the extent to which FDA and SEC regulations, policies, and decisions may become subject to increasing legal challenges, delays, and changes.Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or REMS.Â These regulatory authorities may require precautions or contra indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the product labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.Further, the regulatory authorities may require concurrent approval of a companion diagnostic device. For our product candidates, it may be necessary to use FDA-cleared or FDA-approved diagnostic tests to diagnose patients or to assure the safe and effective use of product candidates in trial subjects. The FDA refers to such tests as in vitro companion diagnostic devices. The FDA has issued guidance describing the agencyâ€™s current thinking about the development and regulation of in vitro companion diagnostic devices. The final guidance articulates a policy position that, when an in vitro diagnostic device is essential to the safe and effective use of a therapeutic product, the FDA generally will require approval or clearance of the diagnostic device at the same time that the FDA approves the therapeutic product. At this point, it is unclear how the FDA will apply this policy to our current or future gene therapy product candidates. Should the FDA deem genetic tests used for diagnosing patients for our therapies to be in vitro companion diagnostics requiring FDA clearance or approval, we may face significant delays or obstacles in obtaining approval of a BLA for our product candidates.58Table of ContentsThe FDA and ex-U.S. regulatory agencies have demonstrated caution in their regulation of gene therapy treatments. Ethical and legal concerns about gene therapy and genetic testing may result in additional regulations or restrictions on the development and commercialization of our product candidates, which may be difficult to predict.â€‹The FDA and ex-U.S. regulatory agencies at both the federal and state level in the United States, U.S. congressional committees, and foreign governments, have expressed interest in further regulating the biotechnology industry, including gene therapy and genetic testing. Any such further regulation may delay or prevent commercialization of some or all of our product candidates.Regulatory requirements in the United States and abroad governing gene therapy products have changed frequently and may continue to change in the future. In addition to the FDA, the Institutional Biosafety Committee and IRB of each institution at which we conduct our planned clinical trials, would need to review the proposed clinical trial to assess the safety of the trial. Within the FDA, the Office of Therapeutic Products, within the Center for Biologics Evaluation and Research, or CBER, consolidates the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee advises CBER on its review. Adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates.These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.â€‹The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last severalÂ years, including for 35Â days beginning on DecemberÂ 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop important activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad and will limit our ability to realize their full market potential.â€‹In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction by jurisdiction basis regarding safety and efficacy. Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and 59Table of Contentsadditional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. In addition, gene therapy products are considered genetically modified organism, or GMO, products and are regulated as such in each country. Designation of the type of GMO product and subsequent handling and disposal requirements can vary across countries and is variable throughout the European Union, or EU. Addressing each specific country requirement and obtaining approval to commence a clinical trial in these countries could result in delays in starting, conducting, or completing a clinical trial. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets and expect to rely on third-party consultants. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.We may not be successful in our efforts to build a pipeline of additional product candidates.â€‹Our business model is centered on developing therapies for patients with CNS disorders by establishing focused selection criteria to select, develop and advance product candidates that we believe will have a higher probability of technical and regulatory success through development into commercialization. We may not be able to continue to identify and develop new product candidates in addition to the pipeline of product candidates that we have established through our collaboration with GTP. As a result of the Outlicense Transaction Agreements, we no longer have a collaboration with GTP and instead have a collaboration with Gemma. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.Risks Related to Our Reliance on Third Partiesâ€‹We currently rely on our collaboration with Gemma for many aspects of our preclinical research and development programs, including for discovering, preclinically developing and conducting IND-enabling studies for our preclinical product candidates and our near-term future pipeline of product candidates. Failure or delay of Gemma to fulfill all or part of its obligations to us under the agreement, a breakdown in collaboration between the parties or a complete or partial loss of this relationship could materially harm our business.â€‹As part of the Outlicense Transaction Agreements, we entered into the Gemma Collaboration Agreement with Gemma to discover and develop certain AAV vector-based therapeutics, and the products developed under such collaboration currently represent all of our product pipeline and research programs. We currently rely on Gemma for preclinical research and development capabilities for new product candidates. Pursuant to the Gemma Collaboration Agreement, Gemma is responsible for discovery, preclinical development activities, including IND-enabling non-clinical studies and research grade manufacturing and other collaborative activities set forth in the plan for the funded research. Either party has the right in certain circumstances to terminate the collaboration pursuant to the terms of the Gemma Collaboration Agreement. If Gemma delays or fails to perform its obligations under the Gemma Collaboration Agreement, disagrees with our interpretation of the terms of the collaboration or our discovery plan or terminates our existing agreement, our future pipeline of product candidates could be significantly adversely affected and our prospects will be materially harmed.The term of the research funding portion of the Gemma Collaboration Agreement, under which we have the ability to acquire exclusive rights to additional gene therapy products for CNS indications, expires in July 2029. If we seek to extend or alter the terms of our collaboration, we will need to negotiate a new or amended agreement, which may not be available to us on equally favorable terms, if at all. Gemma has also entered into collaborations with third parties, including certain of our competitors, addressing targets and disease indications outside the scope of our collaboration. As a result, Gemma may have competing interests with respect to their priorities and resources. We may have disagreements 60Table of Contentswith Gemma with respect to the interpretation of the Gemma Collaboration Agreement, use of resources or otherwise that could cause our relationship with Gemma to deteriorate. As a result, Gemma may reduce their focus on, and resources allocated to, our programs, potentially delaying or terminating our ability to advance product candidates through preclinical studies. If Dr. Wilson were to leave Gemma or to otherwise no longer be meaningfully involved with us, our preclinical research and development capabilities may be substantially reduced. Additionally, as a newly formed Company, Gemma could face operational and financial challenges that could impact its ability to execute under the Gemma Collaboration Agreement.Further, under the Penn License Agreement and the Gemma Collaboration Agreement, Gemma and Penn are primarily responsible for prosecuting and maintaining our licensed intellectual property, and either of them may fail to properly prosecute, maintain or defend such intellectual property. In such event, if we are unable to otherwise maintain or defend such intellectual property, we could face the potential invalidation of the intellectual property or be subjected to litigation or arbitration, any of which would be time-consuming and expensive. To enforce the licensed intellectual property rights under the Penn License Agreement or the Gemma Collaboration Agreement, we will need to coordinate with Penn and Gemma, respectively, which could slow down or hamper our ability to enforce our licensed intellectual property rights. In such an event, we could face increased competition that could materially and adversely affect our business.We rely on third parties to conduct our preclinical studies and clinical trials and rely on them to perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.â€‹Although we have recruited a team that has experience with clinical trials, as a company, we have limited experience in conducting clinical trials. Moreover, we currently rely on third-parties, now primarily Gemma, for our discovery and certain of our preclinical research, and will continue to rely upon medical institutions, clinical investigators, and CROs to conduct clinical trials for our product candidates. We expect to rely heavily on these parties for execution of preclinical and clinical trials for our product candidates and control only certain aspects of their activities. If these parties reduce the levels of efforts and resources to our product candidate activities, prioritize work with a competitor of ours or if a dispute were to arise between us and these parties, they may not meet our expected deadlines or provide us with sufficient materials for our regulatory filings. Nevertheless, we will be responsible for ensuring that each of our preclinical and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.We, Gemma, and our CROs will be required to comply with regulations, including cGCPs for conducting, monitoring, recording and reporting the results of preclinical and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces cGCP regulations through periodic inspections of clinical trial sponsors, principal investigators, and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be

deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with cGCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in the current Good Manufacturing Practices, or cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.Although we currently design and intend to continue designing our planned clinical trials for our product candidates, for the foreseeable future CROs will conduct all of our planned clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third 61Table of Contentsparties to conduct future preclinical studies and clinical trials will also result in less day-to-day control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff.If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any preclinical studies or clinical trials with which such CROs are associated with may be extended, delayed or terminated. In such cases, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates in the subject indication could be harmed, our costs could increase and our ability to generate revenue could be delayed.We rely on third parties to conduct our clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations and prospects.â€‹We rely on third-party clinical investigators, CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of clinical trials of our product candidates. Because we rely and intend to rely on these third parties and will not have the ability to conduct all clinical trials independently, we will have less control over the timing, quality and other aspects of clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our clinical trials, resulting in the clinical trials being delayed or unsuccessful.If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with GLPs and clinical trials to be conducted in accordance with cGCPs, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into alternative arrangements or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially adversely impact our ability to meet our desired clinical development timelines.â€‹62Table of ContentsWe have outlicensed our lysosomal pediatric products to Gemma, a genetic medicines company, and we may in the future enter into collaborations with other third parties for the discovery, development and commercialization of our product candidates. If any of our current or future collaborators cease development efforts under our collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.â€‹Gemma is a newly-formed company with a limited history of operations. If Gemma is not successful in continuing the development and commercialization of the lysosomal pediatric products that we have licensed to them, we will not receive any downstream economic benefit and the products will revert back to us.We may in the future enter into third-party collaborations for research, development and commercialization of other therapeutic technologies or product candidates. Biotechnology companies are our likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements.With Gemma and any future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaboratorsâ€™ abilities to successfully perform the functions assigned to them in these arrangements.â€‹Our current and potential future collaborations involving our product candidates may pose the following risks to us:â€‹â—collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;â—collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaboratorsâ€™ strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;â—collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;â—collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;â—collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;â—collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;â—collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation, indemnification obligations and potential liability;â—disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;â—if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; andâ—collaboration agreements may restrict our right to independently pursue new product candidates.â€‹As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or 63Table of Contentscommercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop our product candidates and research programs, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and maintaining and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.We may not be successful in finding additional collaborators for continuing development of certain of our product candidates or successfully commercializing or competing in the market for certain indications.â€‹We may decide to pursue collaborations with additional pharmaceutical and biotechnology companies for the development and potential commercialization of some of our product candidates. We face significant competition in seeking appropriate collaborators. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaboratorâ€™s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaboratorâ€™s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.We may have conflicts with our collaborators that could delay or prevent the development or commercialization of our product candidates.â€‹We may have conflicts with our collaborators, including Penn and Gemma, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating 64Table of Contentsrevenues: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the relevant agreement.We may in the future seek to engage in strategic transactions to acquire or in-license new products, product candidates or technologies. If we are unable to successfully complete, or realize the benefits from, such transactions it may adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.â€‹From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases, joint ventures and in-licensing of new products, product candidates or technologies that we believe will complement or augment our existing business. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.We cannot assure you that following any such strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our managementâ€™s time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.Risks Related to Manufacturingâ€‹Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.â€‹We currently rely on third parties to develop, manufacture and test clinical supplies of our product candidates, including the materials used to administer our product candidates. For our initial clinical trials, we rely on the manufacturing facility of Catalent Maryland, a unit of Catalent, Inc., or Catalent, for supply of our product candidates. We have limited experience as a company in developing manufacturing facilities. If or when we decide to construct our own manufacturing facility for long-term commercial market supply, we may face delays in building out a plant, constructing new facilities, transferring technology to the facilities or hiring experts to staff and operate the facilities and, accordingly, our production capacity could be limited. We have established internal testing operations supporting our preclinical and clinical manufacturing in addition to using external contract testing labs and established analytical 65Table of Contentsdevelopment and process development capabilities to support our pipeline. The manufacturing processes used to produce our product candidates are complex, novel and have not been validated for commercial use. Many factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers.Our product candidates require processing steps that are more complex than those required for most small molecule drugs. Moreover, unlike small molecules, the physical and chemical properties of a biologic such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product is consistent from lot-to-lot or will perform in the intended manner. For example, we have recently developed a potency assay for release of PBFT02 for late-stage clinical studies and commercialization. While we have received initial positive feedback from the FDA on the suitability of our proposed assay, there can be no assurance that this assay will be approved by the FDA or ensure product potency. Accordingly, we employ multiple steps to control the manufacturing process to assure that the process works consistently and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, low lot yields, product recalls, product liability claims or insufficient inventory. As a result, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet the FDA or other applicable standards or specifications with consistent and acceptable production yields and costs.In addition, the FDA and ex-U.S. regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or ex-

U.S. regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures, low lot yields or product recalls. Lot failures, low lot yields or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.We, or our third-party collaborators, also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements.Any problems in our, or our third-party collaboratorsâ€™, manufacturing process or facilities could result in delays in our planned clinical trials and increased costs, and could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit our access to additional attractive development programs. It could also require us to find alternative manufacturing processes, which may be unavailable to us on attractive terms, or at all. Problems in our manufacturing process could restrict our ability to meet potential future market demand for our products.Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.â€‹As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.66Table of ContentsWe currently rely and expect to continue to rely on third-party manufacturers to produce clinical supply of our product candidates, and we have not entered into binding agreements with any such manufacturers to support commercialization. The competition for gene therapy contract development, manufacturing and testing services is intense. Additionally, these manufacturers do not have experience producing our product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.While we are in the process of establishing manufacturing capability for certain clinical manufacturing activities, we do not currently plan to independently manufacture most of the material for our planned clinical programs. We currently rely, and expect to continue to rely, on third parties for the production of our preclinical study and planned clinical trial materials, including the materials used to administer our product candidates and, therefore, we can control only certain aspects of their activities. The competition for gene therapy contract development, manufacturing and testing is intense. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves, including but not limited to potential competition from other genetic biotechnology companies for the use of such third-party manufacturers. For example, we currently rely on Catalent to manufacture our clinical supply. However, following the recently announced acquisition of Catalent by Novo Holdings A/S, we may face delays or other risks to our manufacturing process depending on any changes implemented as result of such transaction.While we have secured an agreement with Catalent to manufacture clinical supply of our product candidates, we have not yet secured manufacturing capabilities for commercial quantities of our product candidates. We may be unable to negotiate binding agreements with the manufacturers to support our potential commercialization activities at commercially reasonable terms. In addition, under our current agreements with Catalent, (i) we no longer have exclusive access to the dedicated clean room suite and may not be able to secure future capacity or to meet our requirements for future clinical and commercial supply and (ii) we have an exclusive obligation to manufacture certain products with Catalent and therefore we may be unable to work with other third-party manufacturers. As a result, we may be unable to continue to develop and commercialize our products or product candidates.Before any of our third-party manufacturers and suppliers can begin to commercially manufacture our product candidates, including the materials used to administer our product candidates, they must demonstrate to regulatory authorities that the planned chemistry, manufacturing and controls for our gene therapy product candidates meet certain requirements. Manufacturing of product candidates for clinical and commercial purposes must comply with the cGMP and applicable ex-U.S. regulatory requirements. The cGMP requirements govern quality control and documentation policies and procedures. Complying with cGMP and ex-U.S. regulatory requirements will require that we expend time, money and effort in production, recordkeeping and quality control to assure that our product candidates meet applicable specifications and other requirements. Our third-party manufacturersâ€™ also must demonstrate to the FDA and ex-U.S. regulators that they can make the product candidate in accordance with the cGMP requirements as part of a pre-approval inspection prior to FDA or similar ex-U.S. regulatory approval of the product candidate. Failure to pass a pre-approval inspection might significantly delay our ability to begin trials in the respective jurisdiction and FDA and ex-U.S. regulatory approval of our product candidates. If any of our third-party manufacturers fail to comply with these requirements, we would be subject to possible regulatory action, which could limit the jurisdictions in which we are permitted to sell our products. As a result, our business, financial condition and results of operations may be materially harmed.In addition, our third-party manufacturers may fail to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates.Even if our third-party manufacturers comply with applicable regulatory requirements, we cannot assure that they will be able to successfully manufacture additional product candidates at a larger scale in a timely or economical manner, or at all. If they are unable to successfully increase our manufacturing scale or capacity, the development, testing, and clinical 67Table of Contentstrials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.Our third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time-consuming or costly.â€‹Our third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. The operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state, and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.Any contamination in our third partiesâ€™ manufacturing process, shortages of raw materials, labor or reagents or failure of any of our key suppliers to deliver necessary components of our platform could result in delays in our clinical development or marketing schedules.â€‹Given the nature of biologics manufacturing, there is a risk of contamination. Any contamination could materially adversely affect our or our third-party vendorâ€™s ability to produce our gene therapies on schedule and could therefore harm our results of operations and cause reputational damage.The raw materials required in our third-party vendorsâ€™ manufacturing processes are derived from biological sources. We cannot assure that our third-party vendors have or will be able to obtain on commercially reasonable terms, or at all, sufficient rights to these materials derived from biological sources. Such raw materials are difficult to procure and may also be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of our product candidates could adversely impact or disrupt the clinical and commercial manufacturing of our product candidates, which could materially and adversely affect our operating results and development timelines.We rely on third-party suppliers for the supply and manufacture of certain components of our technology. Should our ability to procure these material components from our suppliers be compromised, our ability to continuously operate would be impaired until an alternative supplier is sourced, qualified and tested, which could limit our ability to produce a clinical and commercial supply of our product candidates and harm our business.We depend on third-party suppliers for materials used in the manufacture of our product candidates, and the loss of these third-party suppliers or their inability to supply us with adequate materials could harm our business.â€‹We rely on third-party suppliers for certain materials and components required for the production of our product candidates, including the materials used to administer our product candidates. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of materials involve several risks, including limited control over pricing, availability, and quality and delivery schedules. There is substantial demand and limited supply for certain of the raw materials used to manufacture gene therapy products. As a small company, our negotiation leverage is limited and we are likely to get lower priority than our competitors that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and 68Table of Contentspotential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.Risks Related to Commercializationâ€‹We face significant competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or develop therapies or technologies that are more advanced or effective than ours, which may harm our business and financial condition, and our ability to successfully market or commercialize our product candidates.â€‹The biotechnology and pharmaceutical industries, including the genetic medicines field, are characterized by rapidly changing technologies, competition and a strong emphasis on intellectual property. We are aware of several companies focused on developing gene therapies in various indications as well as several companies addressing methods for modifying genes and regulating gene expression. We may also face competition from large and specialty pharmaceutical and biotechnology companies, academic research institutions, government agencies and public and private research institutions.For the treatment of FTD, there are no approved disease-modifying therapies. We consider our most direct competitors with respect to PBFT02 for the treatment of FTD-GRN to be Prevail Therapeutics Inc. (part of Eli Lilly & Co), which is conducting a Phase 1/2 clinical trial for a gene therapy treatment for FTD-GRN and AviadoBio Ltd, which began enrolling their Phase 1/2 gene therapy trial in patients with FTD-GRN in the second half of 2023. AviadoBio Ltd entered into an exclusive option and licensing agreement with Astellas in October 2024. Alector, Inc. (partnered with GSK plc) is conducting a Phase 3 clinical trial with a humanized anti-human sortilin monoclonal antibody for FTD-GRN. Additional companies, including Kyowa Kirin Co., Ltd. and QurAlis Corporation, are conducting preclinical research using genetic medicine approaches to treat patients with FTD-GRN. Denali Therapeutics Inc. in partnership with Takeda Pharmaceutical Company Limited, is conducting a Phase 1/2 clinical trial for their recombinant progranulin protein. Vesper Bio ApS began Phase 1 enrollment for a small molecule sortilin antagonist program targeting FTD-GRN in the fourth quarter of 2023. We are also aware of other therapeutic approaches in preclinical development that may target FTD-GRN patients including the Arkuda Therapeutics small molecule progranulin enhancer program which entered an exclusive option and asset purchase agreement with Johnson & Johnson Innovative Medicine in the first quarter 2024. With respect to PBFT02 for the treatment of FTD-C9orf72, our clinical stage competitors are Transposon Therapeutics, Inc., which is conducting a Phase 2 trial with a small molecule autophagy modulator for FTD-C9orf72, and Alector, Inc. (partnered with GSK plc) which conducted a Phase 2 clinical trial for latozinemab in FTD-C9orf72. There are other approaches in preclinical development for the treatment of FTD-C9orf72. In addition to the GRN and C9orf72 targeted therapies, there are four clinical stage programs for FTD targeting the TDP-43 pathway.Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical, and other resources than we do, such as larger research and development, clinical, commercial and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, if ever. Additionally, new or advanced technologies developed by our competitors may render our current or future product candidates uneconomical or obsolete, and we may not be successful in commercializing our product candidates against competitors.The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors and others in the medical community.â€‹Ethical, social and legal concerns about gene therapy could result in additional regulations restricting or prohibiting our products. Even with the requisite approvals from the FDA in the United States and other ex-U.S. regulatory authorities, the commercial success of our product candidates will depend, in part, on the acceptance of physicians, patients (which 69Table of Contentsincludes caregivers when applicable) and health care payors of gene therapy products in general, and our product candidates in particular, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of gene therapy products and, in particular, our product candidates, if approved for commercial sale, will depend on several factors, including:â€”the efficacy, durability and safety of such product candidates as demonstrated in clinical trials;â€”the potential and perceived advantages of product candidates over alternative treatments;â€”the cost of treatment relative to alternative treatments;â€”the clinical indications for which the product candidate is approved by the FDA or ex-U.S. regulatory authorities;â€”the willingness of physicians to order genetic testing for potential target patient populations;â€”the willingness of potential patients to have genetic testing and counseling;â€”the willingness of physicians to prescribe new therapies, including therapies using ICM administration;â€—our ability to successfully train neurosurgeons and interventional radiologists in ICM administration of our product candidates;â€”the willingness of the target patient population to try new therapies and a therapy with ICM administration;â€—the prevalence and severity of any side effects;â€—product labeling or product insert requirements of the FDA or ex-U.S. regulatory authorities, including any limitations or warnings contained in a productâ€™s approved labeling;â€—relative convenience and ease of administration;â€—the strength of marketing and distribution support;â€—the timing of market introduction of competitive products and the perceptions of such competitive products compared to our products;â€—publicity concerning our products or competing products and treatments;â€—the pricing of our products, particularly as compared to alternative treatments; andâ€—sufficient third-party payor coverage and adequate reimbursement from government and third-party payors and patientsâ€™ willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement.â€‹Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.â€‹We currently do not have a sales team or marketing team for the sales, marketing, and distribution of any of our product candidates that may receive regulatory approval. In order to commercialize any product candidates after approval, we must build on a territory-by-territory basis sales, reimbursement, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such 70Table of Contentscommercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or

more third parties, our future product revenue will suffer and we may incur significant additional losses.We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.â€‹Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay the pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. The development of our clinical product candidates and ongoing research programs require significant resources. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.Risks Related to Intellectual Property â€‹If we are unable to obtain and maintain patent protection or other necessary rights for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad or our rights under licensed patents is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be adversely affected.â€‹Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the United States and other countries for our current product candidates and future products, as well as our core technologies, including our manufacturing know-how. We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to the development of our business by seeking, maintaining and defending our intellectual property, whether developed internally or licensed from third parties. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of gene therapy. Additionally, for some of our product candidates, we intend to rely on regulatory protection afforded through rare drug designations, data exclusivity and market exclusivity as well as patent term extensions, where available.Currently, most of our intellectual property protection consists of patent applications that we have in-licensed from Penn under the Penn License Agreement. The in-licensed patent applications are directed to certain new AAV capsids, to recombinant AAV viruses, or rAAV, capable of delivering certain genes into human cells to treat disorders of the CNS, to methods of treating those diseases with rAAV, as well as to certain aspects of our manufacturing capabilities and related technologies. Our intellectual property also includes patent applications that we solely own that cover processes that we developed for manufacturing our rAAV products and certain of our product candidates.We also have options under the Gemma Collaboration Agreement to conduct further research into new CNS indications that may create additional intellectual property.The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recentÂ years been the subject of much litigation. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our own or licensed patent applications will mature into issued patents, and cannot provide any assurances that any such patents, if issued, will include claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage. Additionally, patents can be enforced only in those jurisdictions in which the patent has issued. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twentyÂ years after its first nonprovisional U.S. filing. The natural expiration of a patent 71Table of Contentsoutside of the United States varies in accordance with provisions of applicable local law, but is generally 20Â years from the earliest local filing date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.Moreover, our exclusive license under the Penn License Agreement is subject to field restrictions and retained rights, which may adversely impact our competitive position. Our licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates, including biosimilar versions of such products. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties outside our licensed field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.Other parties have developed technologies that may be related or competitive to our own and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and in other jurisdictions are typically not published until 18Â months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether the inventors of our own or licensed patents and applications were the first to make the inventions claimed in those patents or pending patent applications, or that they were the first to file for patent protection of such inventions. Further, we cannot assure you that all of the potentially relevant prior art relating to our own or licensed patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. As a result, the issuance, scope, validity and commercial value of our patent rights cannot be predicted with any certainty. Further, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.In addition, the patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, the scope of the claims initially submitted for examination may be significantly narrowed by the time they issue, if at all. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We cannot provide any assurances that we will be able to pursue or obtain additional patent protection based on our research and development efforts, or that any such patents or other intellectual property we generate will provide any competitive advantage. Moreover, we do not have the right to control the preparation, filing and prosecution of patent applications, or to control the maintenance of the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be filed, prosecuted or maintained in a manner consistent with the best interests of our business.Even if we acquire patent protection that we expect should enable us to maintain competitive advantage, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Third parties, including competitors, may challenge the inventorship, scope, validity, or enforceability thereof, which may result in such patents being narrowed, invalidated or held unenforceable. If issued, our own or licensed patents may be challenged in patent offices in the United States and international markets, or in court. For example, we may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office, or USPTO, challenging the validity of one or more claims of our own or licensed patents, once issued. Such submissions may also be made prior to a patentâ€™s issuance, precluding the granting of a patent based on one of our pending licensed patent applications. We may become involved in opposition, reexamination, inter partes review, post-grant review, derivation, interference, or similar proceedings in the United States or abroad challenging the claims of patents that we have licensed, once issued. Furthermore, patents that we have licensed may be challenged in court, once issued. Competitors may claim that they invented the inventions claimed in such patents or patent applications prior to the inventors of our own or licensed patents, or may have filed patent applications before the inventors of our own or licensed patents did. A competitor may also claim that we are infringing its patents and that we therefore cannot practice our technology as claimed under our own or licensed patent applications and patents, if issued. As a result, one or more claims of our own or licensed patents may be narrowed or invalidated. In 72Table of Contentslitigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents. Even if they are unchallenged, our own or licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our own or licensed patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, even if we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention if the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. Moreover, a third party may develop a competitive product that provides benefits similar to one or more of our product candidates but that uses a vector or an expression construct that falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.Similar risks would apply to any patents or patent applications that we may own or in-license in the future.In addition to patent protection, if any of our product candidates are approved by the FDA as a biological product under a BLA in the United States, we believe the product would qualify for a 12-year period of exclusivity. Other regulatory exclusivities may be available, such as Orphan Drug exclusivity, with analogous data, marketing, and orphan exclusivities in various foreign countries. However, the scope of such regulatory exclusivities is subject to change, and may not provide us with adequate and continuing protection sufficient to exclude others from commercializing products similar to our product candidates.All of our current product candidates and research programs, including for PBFT02, are licensed from or based upon licenses from a third-party and are field limited to certain indications. If the license agreements are terminated or interpreted to narrow our rights, our ability to advance our current product candidates or develop new product candidates based on these technologies will be materially adversely affected.â€‹We currently rely on licenses and sublicenses from third parties, in particular Penn, and will continue to rely on third parties for the research, development, manufacturing and commercialization of our current product candidates. If any of our licenses or relationships or any in-licenses on which our licenses are based are terminated or breached, we may:â—lose our rights to develop and market our current product candidates;â—lose patent or trade secret protection for our current product candidates;â—experience significant delays in the development or commercialization of our current product candidates;â—not be able to obtain any other licenses on acceptable terms, if at all; orâ—incur liability for damages.â€‹Additionally, even if not terminated or breached, our intellectual property licenses or sublicenses may be subject to disagreements over contract interpretation which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations.If we experience any of the foregoing, it could have a materially adverse effect on our business and could force us to cease operations which could cause you to lose all of your investment.If we breach our license agreements it could have a material adverse effect on our commercialization efforts for our product candidates.â€‹If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Our current clinical product candidates, including PBFT02 are, licensed from Penn. Under the Penn License Agreement, we are subject to various obligations, including payment obligations, diligence obligations such as development and commercialization obligations, as well as potential royalty payments and other obligations. If we fail to comply with any of these obligations or otherwise breach our license agreements, our licensors may have the right to terminate the 73Table of Contentsapplicable license in whole or in part. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could harm our business, prospects, financial condition and results of operations.Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:â—the scope of rights granted under the license agreement and other interpretation-related issues;â—whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;â—our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;â—our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;â—the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; andâ—whether and the extent to which inventors are able to contest the assignment of their rights to our licensors.â€‹If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms or at all, we may be unable to successfully develop and commercialize the affected product candidates. In addition, if disputes arise as to ownership of licensed intellectual property, our ability to pursue or enforce the licensed patent rights may be jeopardized. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.Our strategy of obtaining rights to key technologies through in-licenses may not be successful.â€‹We seek to expand our product candidate pipeline in part by in-licensing the rights to key technologies. The future growth of our business will depend in part on our ability to in-license or otherwise acquire the rights to additional product candidates or technologies. We cannot assure you that we will be able to in-license or acquire the rights to any product candidates or technologies from third parties on acceptable terms or at all.The in-licensing and acquisition of these technologies is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire product candidates or technologies that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to license rights to us. Furthermore, we may be unable to identify suitable product candidates or technologies within our area of focus. If we are unable to successfully obtain rights to suitable product candidates or technologies, our business, financial condition and prospects could suffer.Third parties may initiate legal proceedings alleging claims of intellectual property infringement, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.â€‹Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our product candidates and future products and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, future products and technology. Our competitors or other third parties may assert infringement or misappropriation claims against us, alleging that our therapeutics, manufacturing methods, formulations or administration methods are covered by their patents. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing product candidates. For example, a third party previously sent us a letter claiming that the use of our AAVhu68 capsid infringes certain patent claims to which the third party has an exclusive license. While this matter has been resolved and we believe that we would have valid defenses to these and any other such claims; however, if any such claims were ultimately successful, 74Table of Contentswe might require a license to continue to use and sell any product candidates using such AAV vector. Such licenses may not be available on commercially reasonable terms, or at all.Further, we do not know which processes we will use for commercial manufacture of our future products, or which technologies owned or controlled by third parties may prove important or essential to those processes. Given the vast number of patents in our field of technology, we cannot be certain or guarantee that we do not or will not infringe existing patents or that we will not infringe patents that may be granted in the future. Many companies have filed, and continue to file, patent applications related to gene therapy and orphan diseases. Some of these patent applications have already been allowed or issued and others may issue in the future. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take manyÂ years to issue, may be confidential for 18Â months or more after filing and can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use, sale or importation of our product candidates or future products. If a patent holder believes the manufacture, use, sale, offer for sale or importation of one of our product candidates or future products infringes its patent, the patent holder may sue us even if we have licensed other patent protection for our technology. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our licensed patent portfolio may therefore have no deterrent effect.It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before NovemberÂ 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but

incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale, importation or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our future products or the manufacture or use of our future products.Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we were to challenge the validity of an issued U.S. patent in court, such as an issued U.S. patent of potential relevance to some of our product candidates or future products or manufacture or methods of use, we would need to overcome a statutory presumption of validity that attaches to every U.S. patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patentâ€™s claims. There is no assurance that a court would find in our favor on questions of infringement or validity.Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, to infringe a third-partyâ€™s intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any such license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneysâ€™ fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our future products or force us to cease some of our business operations, which could materially harm our business. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. If we lose a foreign patent lawsuit alleging our infringement of a competitorâ€™s patents, we could be prevented from marketing our therapeutics in one or more foreign countries and/or be required to pay monetary damages for infringement or royalties in order to continue marketing. Claims that we have misappropriated the confidential information, trade secrets or other intellectual 75Table of Contentsproperty of third parties could have a similar negative impact on our business. Any of these outcomes would have a materially adverse effect on our business.Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court, or redesign our future products or processes. Patent litigation is costly and time-consuming, and some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. We may not have sufficient resources to bring these actions to a successful conclusion. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts, adversely affect our ability to raise additional funds, and could limit our ability to continue our operations.If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.â€‹In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim that a third-party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing or unwilling to protect trade secrets.Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies and our patent protection could be reduced or eliminated for non-compliance with these requirements.â€‹The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in premature abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure 76Table of Contentsto properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our product candidates, which would have a material adverse effect on our business.We may not be able to protect our intellectual property rights throughout the world.â€‹Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.Most of our in-licensed patent families are pending in major pharmaceutical markets including the United States, Canada, Europe, Japan, Korea, and China, as well as other jurisdictions; we will not be able to enforce the patent in any jurisdictions in which the application has not been filed. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and we or our licensor may be unable to predict and may fail to seek patent protection in jurisdictions in which protection may ultimately be desired.Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.â€‹Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patentâ€™s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or 77Table of Contentscompetitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last forÂ years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.Changes in patent law in the United States and in ex-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.â€‹As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain.Past or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, in MarchÂ 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a â€œfirst to inventâ€ to a â€œfirst-inventor-to-fileâ€ patent system. Under a â€œfirst-inventor-to-fileâ€ system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the â€œfirst-inventor-to-fileâ€ provisions, only became effective in MarchÂ 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.Additionally, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics,Â Inc., the U.S. Supreme Court held that certain claims to DNA molecules are not eligible for patent protection. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also have a material adverse effect on our business, financial condition, results of operations and prospects.â€‹78Table of ContentsWe may be subject to claims asserting that our employees, consultants, advisors or collaborators have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of or other rights to what we regard as our own or licensed intellectual property.â€‹Many of our employees, consultants or advisors, and the employees, consultants or advisors of our licensors, are currently, or were previously, employed at or affiliated with universities, hospitals or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individualâ€™s current or former employer. Moreover, some of our licensors, and our or our licensorsâ€™ employees, consultants or advisors are or have been affiliated or have a contractual relationship with multiple institutions and companies including our competitors and may have or have had an obligation to them. Such institutions and companies could challenge our license rights or our licensorsâ€™ intellectual property ownership rights. Litigation may be necessary to defend against these claims and we may be obligated to indemnify our employees, consultants, advisors or collaborators in certain instances. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.â€‹Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20Â years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.If we do not obtain patent term extension for any product candidates we may develop, our business may be materially harmed.â€‹Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of

1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to fiveÂ years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14Â years from the date of product approval, only one patent per product may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, even if we were to seek a patent term extension, it may not be granted because of, for example, the failure to exercise due diligence during the testing phase or regulatory review process, the failure to apply within applicable deadlines, the failure to apply prior to expiration of relevant patents, or any other failure to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval 79Table of Contentsof competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.Some of the intellectual property rights that we have in-licensed were generated through the use of U.S. government funding and are therefore subject to federal regulations such as â€œmarch-inâ€ rights, certain reporting requirements, and a preference for U.S. based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with ex-U.S. manufacturers.â€‹Some of the intellectual property rights we have in-licensed were generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act, and implementing regulations. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us or our licensors to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i)Â adequate steps have not been taken to commercialize the invention; (ii)Â government action is necessary to meet public health or safety needs; or (iii)Â government action is necessary to meet requirements for public use under federal regulations (also referred to as â€œmarch-in rightsâ€). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. These time limits have recently been changed by regulation, and may change in the future. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with ex-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.Risks Related to Government Regulationâ€‹The pricing, insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.â€‹Our clinical product candidates currently target indications with small patient populations. In order for products that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such products must be higher, on a relative basis, to account for the lack of volume. Accordingly, we (including our sublicensees) will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size. If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved.We expect the cost of a single administration of gene therapy products, such as those we are developing, to be substantial when and if they achieve regulatory approval. Therefore, we expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of any of our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.80Table of ContentsThere is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for MedicareÂ & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, since CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. However, one payorâ€™s determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Further, a payorâ€™s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours since there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS.Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of certain third-party payors, such as health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.In addition to CMS and private payors, professional organizations such as the American Medical Association can influence decisions about reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.Fast Track Designation by the FDA may not lead to a faster development or regulatory review or approval process. â€‹We have obtained Fast Track Designation for PBFT02 for the treatment of FTD-GRN. We may seek Fast Track Designation for other potential indications for PBFT02, or for one or more of our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.81Table of ContentsIf we decide to seek Orphan Drug Designation for some of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity.â€‹We have obtained Orphan Drug Designation, for PBFT02 for the treatment of FTD. We have sought and may continue to seek Orphan Drug Designation for one or more of our other product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user-fee waivers. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs for rare diseases, regardless of whether the drugs are designated for the orphan use. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for sevenÂ years, except in limited circumstances. For large molecule drugs, including gene therapies, sameness is determined based on the principal molecular structural features of a product. As applied to gene therapies, the FDA has recently issued final guidance in which it stated it generally intends to consider certain key features, such as the transgenes expressed by the gene therapy and the vectors used to deliver the transgene, to be principal molecular structural features. With regard to vectors, the FDA generally intends to consider whether two vectors from the same viral class are the same or different on a case-by-case basis. The FDA does not intend to consider minor differences between transgenes and vectors to be different principal molecular structural features. When two gene therapy products express the same transgene and have or use the same vector, determining whether two gene therapies are the same drug may also depend on additional features of the final gene therapy product, such as regulatory elements and the cell type that is transduced (for genetically modified cells). In such cases, FDA generally intends to determine whether two gene therapy products are different on a case-by-case basis.â€‹Although we have obtained Orphan Drug Designation for our clinical product candidates, and even if we obtain Orphan Drug Designation for additional product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. If a competitor with a product that is determined by the FDA to be the same as one of our product candidates obtains marketing approval before us for the same indication we are pursuing and obtains Orphan Drug exclusivity, our product candidate may not be approved until the period of exclusivity ends unless we are able to demonstrate that our product candidate is clinically superior. Even after obtaining approval, we may be limited in our ability to market our product. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain Orphan Drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different principal molecular structural features can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same principal molecular structural features for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for some of our product candidates, we may never receive such designations. Similarly, the European Commission may also designate a product as an orphan drug under certain circumstances. â€‹â€‹82Table of ContentsAny product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.Our product candidates and the activities associated with their development and potential commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMPs, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities and requirements regarding the distribution of samples to physicians and recordkeeping.The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of any approved product. The FDA closely regulates the post-approval marketing and promotion of drugs and biologics to ensure drugs and biologics are marketed only for the approved indications and in accordance with the provisions of the approved product labeling. The FDA imposes stringent restrictions on manufacturersâ€™ communications regarding use of their products. If we promote our product candidates beyond their potentially approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.In addition, later discovery of previously unknown adverse events or other problems with our product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:â—‰restrictions on such product candidates, manufacturers or manufacturing processes;â—‰restrictions on the labeling or marketing of a product;â—‰restrictions on product distribution or use;â—‰requirements to conduct post-marketing studies or clinical trials;â—‰warning or untitled letters;â—‰withdrawal of any approved product from the market;â—‰refusal to approve pending applications or supplements to approved applications that we submit;â—‰recall of product candidates;â—‰fines, restitution or disgorgement of profits or revenues;â—‰suspension or withdrawal of marketing approvals;â—‰refusal to permit the import or export of our product candidates;â—‰product seizure; orâ—‰injunctions or the imposition of civil or criminal penalties.â€‹Non-compliance with European requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with requirements regarding the protection of personal information can also lead to significant penalties and sanctions.Our product candidates for which we intend to seek approval may face competition from biosimilars approved through an abbreviated regulatory pathway.â€‹The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference 83Table of Contentsproduct. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12Â years after the original branded product is approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. We believe that if any of our product candidates is approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider any of our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, an interchangeable biosimilar, once approved, may be substituted under existing law for any one of our reference products in a way that is similar to traditional generic substitution; any non-interchangeable biosimilar products may also be substituted by a health care provider but, under existing law, will not be automatically substituted at the pharmacy. The extent of the impact of such substitution will depend on a number of marketplace and regulatory factors that are still developing. Finally, there has been public discussion of potentially decreasing the period of

exclusivity from the current 12 years. If such a change were to be enacted, our product candidates, if approved, could have a shorter period of exclusivity than anticipated.Enacted and future legislation may affect pricing and third-party payment for our product candidates, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set. The full effect of recent United States healthcare reform and other changes in the healthcare industry, laws, and regulations and in healthcare spending is currently unknown, and the reform and other changes may adversely affect our business model.In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, affect pricing and third-party payment for our product candidates prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and negatively affect our ability to profitably sell any products for which we obtain marketing approval. The commercial potential for our products, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. New laws, regulations, or judicial decisions or new interpretations of existing laws, regulations, or decisions, related to healthcare availability, the method of delivery, or payment for healthcare products and services could adversely affect our business, operations, and financial condition, if and when we are able to obtain marketing approval and commercialize our products.There have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs in general and the cost of pharmaceuticals in particular. For example, the Budget Control Act imposed, subject to certain temporary suspension periods, 2% reductions in Medicare payments to providers per fiscal year starting April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, unless additional Congressional action is taken. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including an alternative rebate calculation for a line extension that is tied to the price increases of the original drug, and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs is eliminated. Elimination of this cap may, in some cases, require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products. It is unclear to what extent these regulations or any future legislation or regulations will affect our business, including our ability to generate revenue and achieve profitability.There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. The FDA released a final rule in September 2020 84Table of Contentsproviding guidance for states to build and submit importation plans for drugs from Canada, and FDA authorized the first such plan in Florida in January 2024.Recently, several healthcare reform initiatives culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which allows, among other things, the U.S. Department of Health and Human Services, or HHS, to negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source biologics that have been approved for at least 11 years (seven years for single-source drugs) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products begin in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations, and by October 1, 2023, each manufacturer of the selected drugs signed a manufacturer agreement to participate in the negotiations. HHS announced the negotiated maximum fair prices by August 2024, and these price caps, which cannot exceed the statutory ceiling price, will come into effect on January 1, 2026. A drug or biological product that has an Orphan Drug Designation for only one rare disease or condition will be excluded from the IRAâ€™s price negotiation requirements, but loses that exclusion if it has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also imposes rebates on Medicare Part B and Part D drugs whose prices have increased at a rate greater than the rate of inflation. In addition, the law eliminates the â€œdonut holeâ€ under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and establishing a new manufacturer discount program, which requires manufacturers that want their drugs to be covered by Medicare Part D to provide statutorily defined discounts to Part D enrollees. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, some significant, including civil monetary penalties. These provisions are taking effect progressively starting in 2023, although they may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits. Thus, it is unclear how the IRA will be implemented but it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. The adoption of restrictive price controls in new jurisdictions, more restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.Further, at the U.S. state level, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discount requirements, marketing cost disclosure and price increase transparency reporting, and programs designed to encourage importation from other countries and bulk purchasing. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services or otherwise negatively impact our business model.Our operations and relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.â€‹Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we obtain marketing approval.Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:â—the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, 85Table of Contentsto induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;â—federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;â—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;â—HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;â—the federal Physician Payment Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Childrenâ€™s Health Insurance Program, with specific exceptions, to report payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advanced practice nurses, and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family, which includes annual data collection and reporting obligations; andâ—analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.â€‹Some state laws require pharmaceutical companies to comply with the pharmaceutical industryâ€™s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Other state laws require reporting of certain pricing information, including price increases and prices of newly launched drugs. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, oversight monitoring, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Businessâ€‹Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.â€‹We are highly dependent on the research and development, clinical and business development expertise of our management, scientific and clinical team. We also benefit from the research expertise of Dr.Â Wilson. In his capacity as a Scientific Advisor, Dr. Wilson is not involved in day-to-day operations and does not have the ability to control or 86Table of Contentssignificantly influence the management or operating policies of the Company. Although we have entered into a consulting agreement with Dr.Â Wilson, he may terminate his relationship with us at any time. Although we have entered into employment letter agreements or employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain â€œkey personâ€ insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and manufacturing strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.Recruiting and retaining qualified scientific, clinical, manufacturing and, if needed, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs, particularly within the gene therapy space. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. Further, the reductions in our workforce announced in March 2022, November 2022, and July 2023 may also make retention of our current personnel both more important and more challenging. These workforce reductions resulted in the loss of longer-term employees, the loss of institutional knowledge and expertise and the reallocation and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Given the complexity of our business, we must continue to implement and improve our managerial, operational and financial systems, manage our facilities and continue to recruit and retain qualified personnel.We may be required to expand our manufacturing, development and regulatory capabilities in the future, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.â€‹We may be required to expand our manufacturing, development and regulatory capabilities in the future, which could result in growth to the number of our employees and the scope of our operations, particularly in the areas of manufacturing and clinical strategy, and growing our capability to conduct clinical trials. We may not be able to effectively manage the expansion of our operations in the future or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.Our internal computer systems, or those of our third-party collaborators or other contractors, may fail or suffer security breaches and cyber attacks, which could result in a material disruption of our development programs.â€‹We believe that we take reasonable steps that are designed to protect the security, integrity and confidentiality of the information we collect, use, store, and disclose, but inadvertent or unauthorized data access may occur despite our efforts. For example, our system protections may be ineffective or inadequate, or we could be impacted by software bugs or other technical malfunctions, as well as employee error or malfeasance. Additionally, privacy and data protection laws are evolving, and it is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data handling safeguards and practices that could result in fines, lawsuits, and other penalties, and significant changes to our or our third-party partners business practices and products and service offerings. To the extent that the measures we or our third-party business partners have taken prove to be insufficient or inadequate, we may become subject to litigation, breach notification obligations, or regulatory or administrative sanctions, which could result in significant fines, penalties, damages, harm to our reputation or loss of patients. While we have not experienced any material losses as a result of any system failure, accident or security breach to date, we have been the subject of certain phishing attempts in the past. If such an event were to occur and cause interruptions in our operations, it could result in a material 87Table of Contentsdisruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. Additionally, a party who circumvents our security measures could, among other effects, appropriate patient information or other proprietary data, cause interruptions in our operations, or expose patients to hacks, viruses, and other disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, insurance coverage to compensate for any losses associated with such events may not be adequate to cover all potential losses. The development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated.â€‹To the extent that any disruption, security breach, or cyber-attack were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Depending on the nature of the information compromised, in the event of a data breach or other unauthorized access to our patient data, we may also have obligations to notify patients and regulators about the incident, and we may need to provide some form of remedy, such as a subscription to credit monitoring services, pay significant fines to one or more regulators, or pay compensation in connection with a class-action settlement (including under the new private right of action under the California Consumer Privacy Act of 2018, or the CCPA, which is expected to increase security breach litigation). Such breach notification laws continue to evolve and may be inconsistent from one jurisdiction to another. Complying with these obligations could cause us to incur substantial costs and could increase negative publicity surrounding any incident that compromises patient data. Additionally, the financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could have an adverse effect on our business, reputation, operating results, and financial condition. â€‹Our ability to utilize our net operating loss carryforwards may be subject to limitation.â€‹As of December 31, 2023, we had federal net operating loss, or NOL, carryforwards of $265.5 million. $0.3 million of the federal NOLs will begin to expire in 2037, if not used prior to that date, and the remainder will carryforward indefinitely. â€‹As of December 31, 2023, we had state NOL carryforwards of $265.5 million, which will begin to expire in 2037, and expire through 2043. â€‹As of December 31, 2023, we had

local NOL carryforwards of $214.5 million, which began to expire in 2024, and expire through 2043. â€‹To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. Under legislative changes made by U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act, or the TCJA, U.S. federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the ability to utilize such federal net operating losses to offset taxable income is limited to 80% of our taxable income before the deduction for such net operating loss carryovers. It is uncertain if and to what extent various states will conform to the TCJA.â€‹Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the IRC, if a corporation undergoes an â€œownership change,â€ generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporationâ€™s ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income and post-change liability may be limited. We have not undertaken a Section 382 study, and it is possible that we have previously undergone one or more ownership changes so that our use of net operating losses is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability 88Table of Contentsto us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. â€‹U.S. federal income tax reform and changes in other tax laws could adversely affect us. â€‹Tax laws are being re-examined and evaluated globally, and tax authorities are increasingly scrutinizing the tax positions of companies. Changes in tax laws and regulations in federal, state, local, and foreign jurisdictions could have material adverse impacts on our business, cash flows, operating results, or financial condition, and could materially affect our tax obligations and effective tax rate. For example, the Tax Cuts and Jobs Act significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. This legislation, among other things, included changes to U.S. federal tax rates, imposed significant additional limitations on the deductibility of interest and the use of net operating losses generated in tax years beginning after December 31, 2017. Beginning in 2022, the Tax Cuts and Jobs Act also eliminated the option to immediately deduct research and development expenditures and required taxpayers to amortize domestic expenditures over five years and foreign expenditures over fifteen years. Changes in corporate tax rates, the realization of net deferred tax assets, and the deductibility of expenses under the Tax Cuts and Jobs Act or future changes in tax laws could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or any newly enacted federal tax legislation. Changes in tax laws or regulations in the various tax jurisdictions we are subject to that are applied adversely to us or our clients could increase the costs of our products and harm our business.Additionally, we use our best judgment in attempting to quantify and reserve for our tax obligations. However, a challenge by a taxing authority, a limitation on our ability to utilize tax benefits such as carryforwards or tax credits, or a deviation from other tax-related assumptions could have a material adverse effect on our business, results of operations, or financial condition.Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.â€‹We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of FDA and ex-U.S. regulators, provide accurate information to the FDA and ex-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, pricing, discounting, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop.â€‹We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. If we cannot successfully defend 89Table of Contentsourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:â—decreased demand for any product candidates that we may develop;â—injury to our reputation and significant negative media attention;â—initiation of investigations by regulators;â—withdrawal of clinical trial participants;â—significant time and expenses to defend the related litigation;â—diversion of management and scientific resources from our business operations;â—substantial monetary awards to trial participants or patients;â—loss of revenue; andâ—the inability to commercialize any product candidates that we may develop.â€‹We currently hold limited product liability insurance coverage. We will need to purchase additional product liability insurance coverage as we expand our clinical trials, and if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A successful product liability claim or series of claims brought against us, could decrease our cash and adversely affect our business and financial condition.We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations that can harm our business.â€‹We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Departmentâ€™s Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. Â§ 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.Risks Related to Our Common Stockâ€‹The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.â€‹Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:â—results of preclinical studies or clinical trials of our product candidates or those of our competitors;â—unanticipated or serious safety concerns related to the use of any of our product candidates;90Table of Contentsâ—adverse regulatory decisions, including failure to receive regulatory approval for any of our product candidates;â—the success of competitive drugs or technologies;â—regulatory or legal developments in the United States and other countries applicable to our product candidates;â—the size and growth of our prospective patient populations;â—developments concerning our collaborators, our external manufacturers or in-house manufacturing capabilities;â—inability to obtain adequate product supply for any product candidate for preclinical studies, clinical trials or future commercial sale or inability to do so at acceptable prices;â—developments or disputes concerning patent applications, issued patents or other proprietary rights;â—the recruitment or departure of key personnel;â—the level of expenses related to any of our product candidates or clinical development programs;â—the results of our efforts to discover, develop, acquire or in-license additional product candidates or drugs;â—actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts or publications of research reports about us or our industry;â—variations in our financial results or those of companies that are perceived to be similar to us;â—changes in the structure of healthcare payment systems;â—market conditions in the biotechnology sector;â—our cash position or the announcement or expectation of additional financing efforts;â—health pandemics could adversely impact our business, including our clinical trials and clinical trial operations;â—general economic, industry and market conditions, including changes in interest rates, market volatility, a potential federal government shutdown and inflation;â—general economic uncertainty and capital markets disruptions, which has been substantially impacted by geopolitical instability due to the ongoing military conflicts around the world; andâ—other factors, including those described in this â€œRisk Factorsâ€ section, many of which are beyond our control.â€‹Our executive officers, directors, principal stockholders and their affiliates exercise significant influence over our company, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.â€‹As of SeptemberÂ 30,Â 2024, our executive officers, directors, beneficial owners of 5% or more of our capital stock and their respective affiliates beneficially owned shares representing a substantial portion of our capital stock.This group of stockholders may have the ability to control us through this ownership position and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.The price of our common stock does not meet the requirements for continued listing on The Nasdaq Global Select Market. If we fail to regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.The continued listing standards of The Nasdaq Global Select Market, require, among other things, that the minimum bid price of a listed companyâ€™s stock be at or above $1.00. On August 1, 2024, the Company received notice from the Listing Qualifications staff of the Nasdaq Stock Market, LLC, that, because the closing bid price for the Companyâ€™s 91Table of Contentscommon stock had fallen below $1.00 per share for 30 consecutive business days, the Company no longer complies with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an initial compliance period of 180 calendar days, or until January 28, 2025, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Companyâ€™s common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to January 28, 2025. If the Company does not regain compliance by January 28, 2025, the Company may be eligible for an additional 180 calendar-day grace period if it applies to transfer the listing of its common stock to the Nasdaq Capital Market. To qualify, the Company is required to meet the continued listing requirements for the market value of its publicly held shares and all other initial listing standards for the Nasdaq Capital Market, except the minimum bid price requirement, and provide written notice of its intention to cure the minimum bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary. We cannot provide any guarantee that we will regain compliance during the grace period or be able to maintain compliance with Nasdaqâ€™s listing requirements in the future. If we are not able to regain compliance during the grace period, or any extension of the grace period for which we may be eligible, our common stock will be subject to delisting. Delisting from The Nasdaq Global Select Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.â€‹We have never declared or paid any cash dividends on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will be limited to the appreciation of stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in value of the stock. We cannot guarantee you that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.If we fail to establish and maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investorsâ€™ views of us and, as a result, the value of our common stock.â€‹Pursuant to SectionÂ 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting within our Form 10-K. However, while we remain either a small reporting or emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be frequently evaluated. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on Nasdaq.We expect to hire additional personnel and may utilize external temporary resources to implement, document and modify policies and procedures to maintain effective internal controls. However, it is possible that we may identify deficiencies and weaknesses in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our financial statements could contain material misstatements that, when discovered 92Table of Contentsin the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.We will continue to incur increased costs as a result of operating as a public company and our management will continue to be required to devote substantial time to new compliance initiatives.â€‹As a public company, particularly after we are no longer an â€œemerging growth company,â€ we will continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act and rulesÂ subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rulesÂ and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We are an â€œemerging growth companyâ€ and â€œsmaller reporting company,â€ and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.We are an â€œemerging growth company,â€ as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (i)Â the last day of the fiscalÂ year in which we have total annual gross revenue of $1.235 billion or more; (ii)Â DecemberÂ 31, 2025; (iii)Â the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous threeÂ years; or (iv)Â the date on which we are deemed to be a large accelerated filer under the rulesÂ of the SEC, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:â—not being required to comply with the auditor attestation requirements of SectionÂ 404 of the Sarbanes-Oxley Act;â—not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditorâ€™s report providing additional information about the audit and the financial statements;â—being permitted to present only twoÂ years of audited financial statements in addition to

any required unaudited interim financial statements with correspondingly reduced â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ disclosure in this Form 10-Q;â—reduced disclosure obligations regarding executive compensation; andâ—exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.â€‹We may choose to take advantage of some, but not all, of the available exemptions. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of SectionÂ 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period to comply with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same adoption timelines for new or revised accounting standards as other public companies that are not emerging growth companies.93Table of ContentsWe are also a â€œsmaller reporting company,â€ meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscalÂ year. We will continue to be a smaller reporting company if either (i)Â the market value of our stock held by non-affiliates is less than $250.0 million or (ii)Â our annual revenue is less than $100.0 million during the most recently completed fiscalÂ year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscalÂ years of audited financial statements in our Annual Report on FormÂ 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.The exclusive forum provisions in our restated certificate of incorporation and amended and restated bylaws may limit a stockholderâ€™s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.â€‹Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, or the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as SectionÂ 22 of the Securities Act, creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the ruleÂ and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rulesÂ and regulations thereunder.In MarchÂ 2020,Â we amended and restated our restated bylaws to provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application ofÂ the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.These choice of forum provisions may limit a stockholderâ€™s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.In addition, SectionÂ 203 of the DGCL may discourage, delay or prevent a change in control of our company. SectionÂ 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.â€‹Provisions in our restated certificate of incorporation and our restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions 94Table of Contentsin which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:â—establish a classified board of directors so that not all members of our board are elected at one time;â—permit only the board of directors to establish the number of directors and fill vacancies on the board;â—provide that directors may only be removed â€œfor causeâ€ and only with the approval of two-thirds of our stockholders;â—require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;â—authorize the issuance of â€œblank checkâ€ preferred stock that our board could use to implement a stockholder rights plan, also known as a â€œpoison pillâ€;â—eliminate the ability of our stockholders to call special meetings of stockholders;â—prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;â—prohibit cumulative voting; andâ—establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.â€‹Moreover, we are governed by the provisions of SectionÂ 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of threeÂ years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.Any of these provisions of our charter documents or Delaware law could, under certain circumstances, depress the market price of our common stock.General Risk Factorsâ€‹We may be subject to securities litigation, which could result in substantial expenses and could divert management attention.â€‹The market price of our common stock has been and may continue to be volatile. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our managementâ€™s attention from other business concerns, which could seriously harm our business.If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.â€‹The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not have any control over the analysts, or the content and opinions included in their reports. If one or more of the analysts covering our business downgrades their evaluations of our stock, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.95Table of ContentsWe are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.â€‹We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the operation of our business, and are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. Each of these constantly evolving laws can be subject to varying interpretations. Additionally, the SEC and many jurisdictions have enacted or may enact laws and regulations requiring companies to disclose or otherwise provide notifications regarding data security breaches. For example, the SEC recently adopted cybersecurity risk management and disclosure rules, which require the disclosure of information pertaining to cybersecurity incidents and cybersecurity risk management, strategy, and governance. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements with inconsistent or conflicting standards.For example, California has enacted the CCPA, which became operative on January 1, 2020 and became enforceable by the California Attorney General on July 1, 2020. Additionally, in the California Privacy Rights Act, or CPRA, which expands upon the CCPA, became effective on January 1, 2023. The CCPA and CPRA require covered companies to, among other things, provide new disclosures to California users, and affords such users new privacy rights such as the ability to opt-out of certain sales of personal information and expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is collected, used, and shared. The CCPA and CPRA provide for civil penalties for violations, as well as a private right of action for security breaches that may increase security breach litigation. Potential uncertainty surrounding the CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and could have a material adverse effect on our business, including how we use personal information, our financial condition, the results of our operations or prospects. Virginiaâ€™s Consumer Data Protection Act, which took effect on January 1, 2023, requires opt-in consent from consumers to acquire and process their sensitive personal information, which includes information revealing a consumerâ€™s physical and mental health diagnosis and genetic and biometric information that can identify a consumer.Other states have passed similar laws, and a number of other states are actively considering bills with similar laws. To the extent multiple state-level laws are later introduced, it may require costly and difficult efforts to achieve compliance with such laws that could expose us to fines and penalties for non-compliance.In the European Economic Area, or the EEA, the General Data Protection Regulation or the GDPR, governs the collection, use, disclosure, transfer or other processing of personal data of European persons. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data processing obligations to the competent national data processing authorities, changes the lawful bases on which personal data can be processed, expands the definition of personal data and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having â€œadequateâ€ data protection laws (sometimes referred to as â€œthird countriesâ€), and imposes strict rules subject to substantial fines for breaches and violations (up to the greater of â‚¬20 million or 4% of our annual worldwide gross revenue). These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices.Additionally, in the United Kingdom, or U.K., the Data Protection Act contains provisions, including its own derogations, for how GDPR is applied in the U.K. We have to continue to comply with the GDPR and also the U.K.â€™s Data Protection Act, with each regime having the ability to fine up to the greater of â‚¬20 million (Â£17 million) or 4% of global turnover.96Table of ContentsAs of January 1, 2024, although effective July 10, 2023, the new EU-U.S. Data Privacy Framework, or DPF, has been recognized as adequate under EU law to allow transfers of personal data from the EU (as well as the U.K. and Switzerland) to certified companies in the U.S. However, the DPF is likely to face legal challenge at the Court of Justice of the European Union which could cause the legal requirements for personal data transfers from the Europe to the U.S. to become uncertain once again. We will monitor these legal developments and continue to use best practices to follow established European legal standards to conduct cross-border transfer of personal data.In addition, while the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis, taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. The use of standard contractual clauses for the transfer of personal data specifically to the United States remains under review by a number of European data protection supervisory authorities, along with those of some other EU member states. German and Irish supervisory authorities have indicated, and enforced in recent rulings, that the standard contractual clauses alone provide inadequate protection for EU-U.S. data transfers. Further, on June 4, 2021 the European Commission finalized new versions of the Standard Contractual Clauses, with the Implementing Decision now in effect as of June 27, 2021. To comply with the Implementing Decision and the new Standard Contractual Clauses, we may need to implement additional safeguards to further enhance the security of data transferred out of the EEA, conduct data transfer impact assessments, and review existing agreements which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. The new standard contractual clauses apply only to the transfer of data outside of the EEA and/or Switzerland and not the United Kingdom, though the U.K.â€™s Information Commissionerâ€™s Officer launched a public consultation on its draft international data transfer agreement in August 2021, and subsequently issued a new international data transfer agreement and addendum which we are required to use under Article 46 of the U.K.GDPR when making restricted data transfers outside of the U.K.The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. We generally seek to comply with industry standards and are subject to the terms of our privacy policies and privacy-related obligations to third parties. We strive to comply with all applicable laws, policies, legal obligations and industry codes of conduct relating to privacy and data protection to the extent possible. However, it is possible that these obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules or our practices. Any failure or perceived failure by us, even if unfounded, to comply with applicable privacy and data security laws and regulations, our privacy policies, or our privacy-related obligations to users or other third parties, or any compromise of security that results in the unauthorized release or transfer of personal information or other sensitive data, may result in governmental enforcement actions, litigation, or public statements against us by consumer advocacy groups or others and could cause our users to lose trust in us, which would have an adverse effect on our reputation and business. Any significant change to applicable laws, regulations or industry practices regarding the use or disclosure of our usersâ€™ data, or regarding the manner in which the express or implied consent of users for the use and disclosure of such data is obtained â€” or in how these applicable laws, regulations or industry practices are interpreted and enforced by state, federal and international privacy regulators â€” could require us to modify our practices, possibly in a material manner, may subject us to regulatory enforcement actions and fines, and may limit our ability to operate using the data that was voluntarily shared with us.97Table of ContentsUnfavorable global economic conditions could adversely affect our business, financial condition or results of operations.â€‹Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets, and, in recent months, the global economy has been impacted by increasing interest rates and inflation. Likewise, the capital and credit markets may be adversely affected by the ongoing conflicts in Ukraine and the Middle East, the possibility of a wider European or global conflict, global sanctions imposed in response thereto, and potential recessions. Moreover, there has been recent turmoil in the global banking system. For example, in March 2023, Silicon Valley Bank, SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. While we did not hold any cash directly at SVB or other banking institutions that have since failed, we regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit and there is no guarantee that the federal government would guarantee all

depositors if such financial institutions were to fail, as they did with SVB depositors, in the event of further bank closures and continued instability in the global banking system. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.â€‹Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facilities, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear, and may heighten or intensify existing risk of natural disasters.Â The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.98Table of ContentsItemÂ 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.Unregistered Sales of Equity SecuritiesNone.ItemÂ 3. Defaults Upon Senior Securities.None.ItemÂ 4. Mine Safety Disclosures.Not applicable.ItemÂ 5. Other Information.During the three months ended September 30, 2024, none of our directors or officers, as defined in Rule 16a-1(f), informed us of the adoption, modification or termination of a â€œRule 10b5-1 trading agreementâ€ or â€œnon-Rule 10b-51 trading agreement,â€ as those terms are defined in Regulations S-K, Item 408.â€‹99Table of ContentsItemÂ 6. Exhibits.The exhibits filed or furnished as part of this Quarterly Report on FormÂ 10-Q are set forth on the ExhibitÂ Index below.â€‹â€‹â€‹â€‹â€‹â€‹â€‹ExhibitNumberÂ Â Â DescriptionÂ Â Â FormÂ Â Â Â FileÂ No.Â Â Â Â ExhibitFilingDateÂ Â Â Â Filed/FurnishedHerewithâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹License Agreement (PBGM01), dated July 31, 2024, by and between the Registrant and Gemma Biotherapeutics, Inc.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹10.2â€ Ë„â€‹Exclusive License Agreement (PBKR03), dated July 31, 2024, by and between the Registrant and Gemma Biotherapeutics, Inc.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹10.3â€ Ë„â€‹Exclusive License Agreement (PBML04), dated July 31, 2024, by and between the Registrant and Gemma Biotherapeutics, Inc.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹10.4â€ Ë„â€‹Transition Services Agreement, dated July 31, 2024, by and between the Registrant and Gemma Biotherapeutics, Inc.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹10.5â€ Ë„â€‹Research, Collaboration & License Agreement, dated July 31, 2024, by and between the Registrant and Gemma Biotherapeutics, Inc.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹10.6â€ Ë„â€‹Second Amended and Restated Research, Collaboration & License Agreement, dated July 31, 2024, by and between the Registrant and the Trustees of the University of Pennsylvaniaâ€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹31.1â€‹Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹31.2â€‹Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹32.1*â€‹Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹100Table of Contents32.2*â€‹Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹101.INSâ€‹Inline XBRL Instance Documentâ€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹101.SCHâ€‹Inline XBRL Taxonomy Extension Schema Documentâ€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹101.CALâ€‹Inline XBRL Taxonomy ExtensionCalculation Linkbase Documentâ€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹101.DEFâ€‹Inline XBRL Taxonomy Extensionâ€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹â€‹Definition Linkbase Documentâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹101.LABâ€‹Inline XBRL Taxonomy Extension LabelLinkbase Documentâ€‹â€‹â€‹â€‹â€‹â€‹â€‹X101.PREâ€‹Inline XBRL Taxonomy ExtensionPresentation Linkbase Documentâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹X104â€‹Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)â€‹â€‹â€‹â€‹â€‹â€‹â€‹Xâ€‹addâ€‹â€‹â€‹â€ â€‹Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.Ë„â€‹Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.*â€‹This certification is deemed not filed for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.â€‹â€‹â€‹101Table of ContentsSIGNATURESPursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.â€‹â€‹â€‹â€‹â€‹PASSAGE BIO,Â INC.â€‹â€‹â€‹â€‹Date: November 13, 2024â€‹By:/s/ William Chou, M.D.â€‹â€‹â€‹William Chou, M.D.â€‹â€‹â€‹President and Chief Executive Officerâ€‹â€‹â€‹â€‹â€‹Date: November 13, 2024â€‹By:/s/ Kathleen Borthwickâ€‹â€‹â€‹Kathleen Borthwickâ€‹â€‹â€‹Chief Financial Officerâ€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹102â€ŒExhibit 10.1â€‹Execution VersionConfidentialâ€‹â€‹CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT PASSAGE BIO, INC. TREATS AS PRIVATE OR CONFIDENTIAL.â€‹EXCLUSIVE LICENSE AGREEMENTby and betweenPassage Bio, Inc.andGemma Biotherapeutics, INC.July 31, 2024â€‹â€‹â€‹â€‹â€ŒExecution VersionConfidentialTABLE OF CONTENTSPageArticle 1 DEFINITIONS & INTERPRETATIONâ€Œ2Article 2 LICENSEâ€Œ152.1 Exclusive License to Gemmaâ€Œ152.2 Retained Rightsâ€Œ152.3 Right to Sublicenseâ€Œ152.4 Right to Subcontractâ€Œ162.5 Right of Access and Referenceâ€Œ172.6 No Implied Licensesâ€Œ172.7 Upstream Licenseâ€Œ172.8 Third Party Licensesâ€Œ18Article 3 EXCLUSIVITYâ€Œ193.1 Exclusivityâ€Œ183.2 Exception for Change of Controlâ€Œ18Article 4 GOVERNANCEâ€Œ194.1 Alliance Managersâ€Œ194.2 Cooperation with UPenn Agreement Committeesâ€Œ19Article 5 PAYMENTSâ€Œ195.1 Product Supply for Clinical Studiesâ€Œ195.2 Development and Regulatory Milestonesâ€Œ195.3 Sales Milestonesâ€Œ205.4 Royalty Paymentsâ€Œ205.5 FDA Priority Review Voucherâ€Œ225.6 Payment Termsâ€Œ225.7 Payment Currency; Exchange Rate; Offsetâ€Œ235.8 Late Paymentsâ€Œ235.9 Payments to Third Partiesâ€Œ235.10 Accountingâ€Œ245.11 Records and Audit Rightsâ€Œ245.12 Taxesâ€Œ255.13 Blocked Currencyâ€Œ25Article 6 DEVELOPMENT AND COMMERCIALIZATIONâ€Œ256.1 Development Planâ€Œ256.2 Clinical Developmentâ€Œ256.3 Commercializationâ€Œ266.4 Manufacturingâ€Œ266.5 Regulatoryâ€Œ266.6 General Diligenceâ€Œ266.7 Diligence Eventsâ€Œ26iâ€‹â€‹â€‹â€‹6.8 Progress Reportsâ€Œ27Article 7 CONFIDENTIALITYâ€Œ277.1 Confidential Informationâ€Œ277.2 Duty of Confidence; Exceptionsâ€Œ287.3 Authorized Disclosuresâ€Œ287.4 Prior Confidentiality Agreementsâ€Œ297.5 Public Disclosures; Securities Filingsâ€Œ297.6 Use of Namesâ€Œ30Article 8 INTELLECTUAL PROPERTYâ€Œ308.1 Ownershipâ€Œ308.2 Patent Prosecution and Maintenanceâ€Œ308.3 Cooperation for Patent Extensionsâ€Œ318.4 Patent Listingsâ€Œ318.5 Common Interest Disclosuresâ€Œ318.6 Patent Enforcementâ€Œ318.7 Infringement of Third Party Rightsâ€Œ328.8 Patent Markingâ€Œ338.9 Trademarksâ€Œ33Article 9 REPRESENTATIONS, WARRANTIES, AND COVENANTSâ€Œ339.1 Representations and Warranties of Each Partyâ€Œ339.2 Representations and Warranties of Passageâ€Œ349.3 Mutual Covenantsâ€Œ349.4 Passage Covenantsâ€Œ359.5 Gemma Covenantsâ€Œ359.6 No Other Warrantiesâ€Œ35Article 10 INDEMNIFICATIONâ€Œ3610.1 Indemnification by Gemmaâ€Œ3610.2 Indemnification by Passageâ€Œ3710.3 Procedureâ€Œ3710.4 Insuranceâ€Œ3810.5 Limitation of Liabilityâ€Œ39Article 11 TERM AND TERMINATIONâ€Œ3911.1 Termâ€Œ3911.2 Termination for Diligence Event Failureâ€Œ4011.3 Termination for Convenience; Termination for Causeâ€Œ4011.4 Termination for Bankruptcyâ€Œ4011.5 Termination for Patent Challengeâ€Œ4111.6 Full Force and Effect During Notice Periodâ€Œ4111.7 Effect of Terminationâ€Œ4211.8 Program Reversionâ€Œ4311.9 Confidential Informationâ€Œ4311.10 Termination Not Sole Remedyâ€Œ43iiâ€‹â€‹â€‹â€‹11.11 Survivalâ€Œ43Article 12 MISCELLANEOUSâ€Œ4312.1 Assignmentâ€Œ4412.2 Use of Affiliatesâ€Œ4412.3 No Discriminationâ€Œ4412.4 Severabilityâ€Œ4412.5 Governing Law; English Languageâ€Œ4412.6 Dispute Resolutionâ€Œ4512.7 Waivers and Amendmentsâ€Œ4612.8 Relationship of the Partiesâ€Œ4612.9 Noticesâ€Œ4612.10 No Third Party Beneficiary Rightsâ€Œ4712.11 Further Assurancesâ€Œ4712.12 Entire Agreementâ€Œ4712.13 Counterpartsâ€Œ4712.14 Expensesâ€Œ4812.15 Constructionâ€Œ4812.16 Interpretationâ€Œ4812.17 Cumulative Remediesâ€Œ4812.18 Exportâ€Œ48â€‹iiiâ€‹â€‹ConfidentialEXCLUSIVE LICENSE AGREEMENTThis Exclusive License Agreement (this â€œAgreementâ€) is entered into as of July 31, 2024 (the â€œEffective Dateâ€), by and between Passage Bio, Inc., a corporation organized under the laws of Delaware (â€œPassageâ€), with offices at 2005 Market St., 39th Floor, Philadelphia, PA 19103, and Gemma Biotherapeutics, Inc., a Delaware corporation (â€œGemmaâ€), with offices at 1831 Delancey Place, Philadelphia, PA 19103. Â Passage and Gemma may be referred to in this Agreement individually as a â€œPartyâ€ or collectively as the â€œParties.â€ BACKGROUNDWHEREAS, Passage is a biopharmaceutical company with expertise in the development, manufacture and commercialization of human therapeutic products for the treatment of genetic disorders;WHEREAS, concurrently with the execution of this Agreement, Passage and The Trustees of the University of Pennsylvania (â€œPennâ€) are also entering into that certain Second Amended and Restated Research, Collaboration & License Agreement, effective as of September 18, 2018, and amended and restated as of the Effective Date (as amended and restated, the â€œUPenn Agreementâ€);WHEREAS, concurrently with the execution of this Agreement, Passage and Gemma are also entering into (a) that certain Exclusive License Agreement, pursuant to which Passage will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for Krabbe disease (globoid cell leukodystrophy), and (b) that certain Exclusive License Agreement, pursuant to which Passage will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for Metachromatic leukodystrophy;WHEREAS, the programs contemplated by this Agreement are of mutual interest to Passage and Gemma, and may benefit Passage and Gemma through the creation or discovery of new inventions and the development and commercialization of Licensed Products (as defined herein) for the Indication (as defined herein);WHEREAS, Gemma wishes to obtain from Passage worldwide, exclusive and non-exclusive licenses to rights granted to Passage under the UPenn Agreement and certain other intellectual property rights owned or controlled by Passage, to develop, manufacture and commercialize Licensed Products for the Indication, and Passage is willing to grant such licenses to Gemma in accordance with the terms and conditions set forth herein; andWHEREAS, concurrently with the execution of this Agreement, Passage and Gemma are also entering into the Transition Services Agreement (as defined herein);NOW THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:â€‹â€‹â€‹Article 1â€‹DEFINITIONS & INTERPRETATIONWhenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, whether used in the singular or plural, shall have the meanings specified.1.1â€œAAAâ€ has the meaning set forth in Section 12.6.2(b).1.2â€œAcquirorâ€ means a Third Party that acquires a Party through a Change of Control, together with any Affiliates of such Third Party existing immediately prior to the consummation of the Acquisition. Â For clarity, an â€œAcquirorâ€ of a Party shall exclude the Party and all of its Affiliates existing immediately prior to the consummation of the Acquisition. Â 1.3â€œAffiliateâ€ means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. Â For the purposes of this Section 1.3, the word â€œcontrolâ€ (including, with correlative meaning, the terms â€œcontrolled byâ€ or â€œunder common control withâ€) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such Person, by contract or otherwise.1.4â€œAlliance Managerâ€ has the meaning set forth in Section 4.1.1.5â€œArising Know-Howâ€ means any and all Know-How, whether or not patentable, generated, created, developed, conceived, reduced to practice, or otherwise made during the Term by or on behalf of Gemma, its Affiliates or Sublicensees in the performance of activities under this Agreement.1.6â€œAuditing Partyâ€ has the meaning set forth in Section 5.11.2. 1.7â€œBiosimilar Actionâ€ has the meaning set forth in Section 8.6.4.1.8â€œBLAâ€ means (a) a biologics license application as that term is used and defined in the PHS Act and the regulations promulgated thereunder, (b) a marketing authorization application in the European Union, or (c) any equivalent or comparable application, registration or certification in any other country or region.1.9â€œBusiness Dayâ€ means a day other than a Saturday, Sunday, or other day on which banking institutions in Philadelphia, PA, USA are authorized or required by Law to remain closed.1.10â€œCalendar Quarterâ€ mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31 of each Calendar Year.1.11â€œCalendar Yearâ€ means each successive period of twelve (12) months commencing on January 1 and ending on December 31.1.12â€œCDAâ€ has the meaning set forth in Section 7.4.2â€‹â€‹â€‹1.13â€œGCPâ€ means the applicable then-current standards for clinical activities for pharmaceuticals or biologicals, as set forth in the FD&C Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good clinical practice as are required by any Regulatory Authority in such country.1.14â€œGLPâ€ means the current good laboratory practice regulations promulgated by the FDA, published at 21 US C.F.R. Â§ 58, and equivalent non-United States regulations and standards in or for the Territory, as applicable, as such current laboratory practices, regulations and standards may be amended from time to time.1.15â€œGMPâ€ means those current practices, as amended from time to time, related to the manufacture of pharmaceutical or biological products and any precursors thereto promulgated in guidelines and regulations of standard compilations, including the cGMP Rules of the World Health Organization, the United States Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (established by the United States Department of Health and Human Services), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical or biological products, and equivalent guidelines, regulations and standards in or for the Territory, as such guidelines, regulations and standards may be amended from time to time.1.16â€œChallengeâ€ means, with respect to a Patent Right, that Gemma or a Sublicensee (including sub-Sublicensees) will be deemed to have made a â€œChallengeâ€ of such Patent Rights if Gemma or such Sublicensee (including sub-Sublicensees), respectively: (a) institutes or voluntarily joins as a party to, or causes its counsel to institute on Gemmaâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, any interference, opposition, re-examination, post-grant review or similar proceeding with respect to any such Patent Right with the US Patent and Trademark Office or any foreign patent office; or (b) makes any filing or institutes or voluntarily joins as a party to any legal proceeding, or causes its counsel to make any filing or institute or voluntarily join as a party to any legal proceeding on Gemmaâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, with a court or other Governmental Body (including, without limitation, the US Patent and Trademark Office or any foreign patent office) having authority to determine the validity, enforceability or scope of such Patent Right, in which one or more claims or allegations challenges the validity or enforceability of any such Patent Right.1.17â€œChange of Controlâ€ with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date: Â (a)any Third Party â€œpersonâ€ or â€œgroupâ€ (as such terms are defined below) (i) is or becomes, through one or a series of transactions, the â€œbeneficial ownerâ€ (as defined below), directly or indirectly, of the then-outstanding shares of common stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total then-outstanding common stock (or foreign equivalent thereof) (the â€œOutstanding Common Stockâ€), (ii) is or becomes, through one or a series of transactions, the â€œbeneficial ownerâ€, directly or indirectly, of shares of securities, capital stock or other interests (including partnership interests) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) then-outstanding and normally entitled (without regard to the 3â€‹â€‹occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (â€œOutstanding Voting Stockâ€) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total voting power of all Outstanding Voting Stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party), or (iii) has the power, directly or indirectly, to elect a majority of the members of the Partyâ€™s (or any direct or indirect parent entities or ultimate parent entities of such Party) board of directors (or similar governing body); or (b)such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) enters into a merger, consolidation or similar transaction with a Person (whether or not such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) is the surviving entity) (a â€œBusiness Combinationâ€), in each case, unless, following such Business Combination, (i) the individuals and entities who were the beneficial owners, respectively, of the Outstanding Common Stock and Outstanding Voting Stock of such Party (and the ultimate parent entity thereof) immediately prior to such Business Combination beneficially own, directly or indirectly, fifty percent (50%) or more of, respectively, (1) the then-outstanding shares of common stock (or foreign equivalent thereof) and (2) the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of directors, of the corporation or other entity resulting

from such Business Combination (and the ultimate parent entity thereof), and (ii) fifty percent (50%) or more of the members of the board of directors (or similar governing body) of the corporation or other entity resulting from such Business Combination (and ultimate parent entity thereof, as applicable) were members of the board of directors (or similar governing body) of such Party (or ultimate parent entity of such Party, as applicable) at the time of the execution of the initial agreement, or became members of the board of directors of such corporation or other entity by virtue of the action of the board of directors (or similar governing body) of such Party (or ultimate parent entity), providing for such Business Combination; or (c)such Party (and its Affiliates) sells, exchanges, or otherwise transfers to any Third Party, directly or indirectly (including through the transfer of shares or other ownership interests in Affiliates), in one or a series of transactions, the properties and assets representing all or substantially all of such Partyâ€™s total assets (together with all or substantially all of the properties and assets of its Affiliates). For the purpose of this definition of Change of Control, (x) â€œpersonâ€ and â€œgroupâ€ have the meanings given such terms under Sections 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term â€œgroupâ€ includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act; (y) a â€œbeneficial ownerâ€ shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms â€œbeneficially ownedâ€ and â€œbeneficially ownâ€ shall have meanings correlative to that of â€œbeneficial owner.â€ 1.18â€œClinical Studyâ€ means a Phase 1 Study, Phase 1/2 Study, Phase 2 Study, or Phase 3 Study, or such other study in humans that is conducted in accordance with cGCP and is designed to generate data in support or maintenance of an application for Regulatory Approval.1.19â€œCombination Productâ€ means a Licensed Product that is delivered with [*] active 4â€‹â€‹â€‹ingredients or other items or services incident to the administration of any such Licensed Product (with or without [*] such other active ingredients), [*], in each such case when any of the foregoing are co-formulated, co-packaged or sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).1.20â€œCommercializeâ€ means any and all activities directed to the offering for sale and sale of a pharmaceutical or biological product, including activities directed to marketing, promoting, advertising, detailing, storing, distributing, importing, exporting, selling, and offering to sell (including receiving, accepting, and filling orders), booking and recording sales, interacting with Regulatory Authorities regarding any of the foregoing and seeking Pricing and Reimbursement Approvals. Â â€œCommercializationâ€ and â€œCommercializingâ€ have a corresponding meaning. 1.21â€œCommercially Reasonable Effortsâ€ means the efforts and resources that a similarly situated biotechnology company would use for its own internally discovered technology of similar commercial potential at a similar stage of development, taking into account the likely timing of the technologyâ€™s entry into the market and any patent and other proprietary position, safety and efficacy, product profile, and the then-current competitive and regulatory environments for the product. Â Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the performing Party (a) promptly assign responsibility for such obligation to specific employee(s) who are accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.1.22â€œCompeting Productâ€ means any product [*].1.23â€œCompetitive Infringementâ€ has the meaning set forth in Section 8.6.1.1.24â€œCompulsory Licenseâ€ means a compulsory license under the Licensed UPenn Patents obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in any country.1.25â€œConfidential Informationâ€ has the meaning set forth in Section 7.1.1.26â€œControlâ€ means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without (i) violating the terms of any other agreement or other arrangement with any Third Party from whom the Party or its Affiliate acquired such intellectual property rights, (ii) requiring additional obligations, liabilities or financial consideration to such Third Party in connection with the grant of such license or sublicense (other than consideration for which the Party or its Affiliate agrees to bear the entire cost), or (iii) violating the terms of, or requiring additional obligations, liabilities or financial consideration to a Third Party under, [*]. Â â€œControlledâ€ has a corresponding meaning.1.27â€œCoverâ€ means (a) with respect to a claim of an issued Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such 5â€‹â€‹â€‹compound or product would infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof), or (b) with respect to a claim of a pending Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would, if such claim were to issue in its current form, infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof). Â â€œCoveredâ€ has a corresponding meaning.1.28â€œCROâ€ means a Third Party contract resesarch organization (for clarity, excluding consultants).1.29â€œData Protection Lawsâ€ has the meaning set forth in Section 9.3.1.1.30â€œDevelopâ€ means any and all pre-clinical, non-clinical and clinical research and development activities for a pharmaceutical or biological product, including activities related to preclinical research and studies, Clinical Studies, toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies, supply of such product for use in the foregoing activities (including placebos and comparators), statistical analyses, the preparation and submission of INDs, MAAs and other Regulatory Materials for the purpose of obtaining, registering and maintaining Regulatory Approval of such product, as well all interactions with Regulatory Authorities with respect to the foregoing. Â â€œDevelopingâ€ and â€œDevelopmentâ€ have a corresponding meaning. 1.31â€œDevelopment Milestone Eventâ€ has the meaning set forth in Section 5.2. 1.32â€œDevelopment Milestone Paymentâ€ has the meaning set forth in Section 5.2. 1.33â€œDisputeâ€ has the meaning set forth in Section 12.6.1. 1.34â€œDivestitureâ€ means, with respect to a Competing Product, (a) [*] (i) [*], or (ii) [*], or (b) [*] with respect to such Competing Product. Â [*]. Â â€œDivestâ€ has a corresponding meaning. Â 1.35â€œElectronic Deliveryâ€ has the meaning set forth in Section 12.13.1.36â€œEMAâ€ means the European Medicines Agency and any successor entity thereto.1.37â€œEnforcement Actionâ€ means a legal action to enforce the Licensed UPenn Patents with respect to Competitive Infringement. 1.38â€œEuropean Unionâ€ or â€œEUâ€ means the European Union. 1.39â€œExclusivity Periodâ€ has the meaning set forth in Section 3.1.1.40â€œExecutive Officersâ€ means Gemmaâ€™s Chief Executive Officer, or her or his designee, and Passageâ€™s Chief Executive Officer, or her or his designee, provided that any such designee must have decision-making authority on behalf of the applicable Party.1.41â€œFD&C Actâ€ means the United States Federal Food, Drug and Cosmetic Act, as amended.6â€‹â€‹â€‹1.42â€œFDAâ€ means the United States Food and Drug Administration and any successor entity thereto.1.43â€œField of Useâ€ means all prophylactic, diagnostic and therapeutic uses in humans. Â For clarity, [*].1.44â€œFirst Commercial Saleâ€ means, on a country-by-country basis, the first commercial transfer or disposition for value of a Licensed Product in such country to a Third Party by Gemma, or any of its Affiliates or Sublicensees, in each case, after Regulatory Approval for such Licensed Product has been obtained for such country.1.45â€œFPFDâ€ means, with respect to a Licensed Product and a Clinical Study, the first dosing of the first patient in such Clinical Study.1.46â€œFTEâ€ means an individual employee of Passage or its Affiliates.1.47â€œGAAPâ€ means United States generally accepted accounting principles applied on a consistent basis.1.48â€œGemma Collaboration Know-Howâ€ means any and all Arising Know-How. 1.49â€œGemma Collaboration Patentsâ€ means any and all Patent Rights that claim Gemma Collaboration Know-How.1.50â€œGemma Indemniteeâ€ has the meaning set forth in Section 10.2. 1.51â€œGeneric Productâ€ means, with respect to a particular Licensed Product in a particular country or regulatory jurisdiction, a generic or biosimilar pharmaceutical product, that is not produced, licensed or owned by Gemma, any of its Affiliates or Sublicensees, that: (a) [*]; and (b) is approved for use in such country or regulatory jurisdiction by a Regulatory Authority by referencing the prior approval, in whole or part, or safety and efficacy data submitted in support of the prior approval, of a Licensed Product. Â Generic Product includes, but is not limited to, any pharmaceutical products for which Regulatory Approval is obtained via: (i) [*]; or (ii) [*].1.52â€œGovernmental Bodyâ€ means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.1.53â€œINDâ€ means an Investigational New Drug Application as defined in the FD&C Act and the regulations promulgated thereunder, or the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, including a Clinical Trial Authorization to the European Medicines Agency, the filing of which is necessary to initiate or conduct clinical 7â€‹â€‹â€‹testing of a pharmaceutical product in humans in such jurisdiction.1.54â€œIndemnified Partyâ€ has the meaning set forth in Section 10.3.1.1.55â€œIndemnifying Partyâ€ has the meaning set forth in Section 10.3.1.1.56â€œIndicationâ€ means GLB1 Deficiency, for GM1 gangliosidosis-1 and mucopolysaccharidosis type IV (MPS IV) through [*]. 1.57â€œKnow-Howâ€ means any proprietary or confidential scientific or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form, including inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know-how, trade secrets, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, physical and analytical, safety, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process and development information, results and data. Â Know-How excludes Materials and Patent Rights.1.58â€œLawâ€ or â€œLawsâ€ means all applicable laws, statutes, rules, regulations, ordinances, and other pronouncements having the binding effect of law of any Governmental Body.1.59â€œLicenseâ€ has the meaning set forth in Section 2.1.1.60â€œLicensed Compoundâ€ means PBGM01, as more fully described in Schedule 1.60.1.61â€œLicensed Know-Howâ€ means the Licensed UPenn Know-How and Passage Know-How.1.62â€œLicensed Product(s)â€ means any (a) process, service or method covered by a Valid Claim of a UPenn Patent or whose use or practice would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim of a UPenn Patent, or would infringe a Valid Claim of a UPenn Patent once issued (â€œMethodâ€); (b) article, composition, apparatus, substance, chemical or any other material covered by a Valid Claim of a UPenn Patent or whose manufacture, import, use, offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim of a UPenn Patent or would infringe a Valid Claim of a UPenn Patent once issued; (c) service, article, composition, apparatus, chemical, substance or any other material made, used or sold by or utilizing or practicing a Method, or (d) any product that incorporates or makes use or is made through use of UPenn Know-How or Passage Know-How, in each case (a) through (d), for the Indication. Notwithstanding the foregoing, the Licensed Products shall include any product containing or comprising the Licensed Compound (alone or in the form of a Combination Product) in all forms, presentations, formulations, methods of administration and dosages.8â€‹â€‹â€‹1.63â€œLicensed UPenn Know-Howâ€ means all UPenn Know-How that is necessary to Develop, Manufacture or Commercialize the Licensed Products for the Indication.1.64â€œLicensed UPenn Patentsâ€ means all UPenn Patents that are necessary to Develop, Manufacture or Commercialize the Licensed Products for the Indication.1.65â€œLossesâ€ has the meaning set forth in Section 10.1.1. 1.66â€œMAAâ€ means (a) a Biologics License Application (as defined in the PHS Act) or New Drug Application (as defined in the FD&C Act) filed with the FDA to gain approval to market a biological or pharmaceutical product in the US, (b) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure to gain approval to market a biological or pharmaceutical product in the EU, or (ii) a Regulatory Authority in any EU country if the centralized EMA filing procedure is not used to gain approval to market a biological or pharmaceutical product in the EU, or (c) any equivalent application or request for authorization filed in support of approval to market a biological or pharmaceutical product in any country, in each case ((a) through (c)), including any amendments and supplements thereto but excluding applications for Pricing and Reimbursement Approval. 1.67â€œMajor Marketâ€ means United States, Japan, France, Germany, Spain, Italy, and the United Kingdom.1.68â€œManufactureâ€ means all activities in connection with the manufacture of a pharmaceutical or biological product, including the processing, formulating, testing (including quality control, quality assurance and lot release testing), bulk packaging, filling, finishing, packaging, labeling, inspecting, receiving, storage, release, shipping and delivery, sourcing of materials, process qualification, validation and optimization, and stability testing of such product. Â â€œManufacturingâ€ and â€œManufacturedâ€ have a corresponding meaning.1.69â€œMaterialsâ€ means any and all biological and other physical materials.1.70â€œNet Salesâ€ means the gross consideration invoiced or received by Gemma or any of its Affiliates or Sublicensees (including all sub-Sublicensees) for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary:(a)trade discounts, including trade, cash and quantity discounts or rebates, credits, or refunds;(b)allowances or credits actually granted upon claims, returns or rejections of products;(c)charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the Sale, transportation, delivery or return of such Licensed Product;9â€‹â€‹â€‹(d)customs duties, sales, excise and use taxes actually paid in connection with the transportation, distribution, use or Sale of such Licensed Product (but excluding what is commonly known as income taxes); and(e)bad debt expense and amounts actually written off by reason of uncollectible debt not to exceed [*] of the Net Sales of Licensed Product.Even if there is overlap between any of the deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation.In the case of a Combination Product, the Parties shall negotiate in good faith, at the latest [*] before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, as the case may be, based on the fair market value of such components for the purposes of determining a product-specific allocation of such Net Sales. Â Payments related to such Combination Product under this Agreement, including Royalties and milestone payments, will be calculated, due and payable based only on the portion of such Net Sales so allocated to a Licensed Productâ€™s components.In case of disagreement and failure by the Parties to agree upon an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, [*].1.71â€œNew License Agreementâ€ has the meaning set forth in Section 11.7.2.1.72â€œNon-Exclusively Licensed Penn IPâ€ has the meaning set forth in Section 2.1.1.73â€œPassage Indemniteeâ€ has the meaning set forth in Section 10.1.1. 1.74â€œPassage Know-Howâ€ means all Know-How Controlled by Passage or any of its Affiliates as of the Effective Date that (a) is necessary to Develop, Manufacture or Commercialize the Licensed Compound for the Indication, or (b) [*], in each case (a) and (b), other than any Licensed UPenn Know-How.1.75â€œPassage Technologyâ€ means the Licensed Know-How and Licensed UPenn Patents.1.76â€œPatent Right(s)â€ means (a) patents and patent applications, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part, reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing, and (b) all official correspondence relating to the foregoing.1.77â€œPatent Term Extensionâ€ has the meaning set forth in Section 8.3. 1.78â€œPersonâ€ means any natural person, corporation, firm, business trust, joint venture, 10â€‹â€‹â€‹association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.1.79â€œPersonal Dataâ€ has the meaning set forth in Section 9.3.1. 1.80â€œPhase 1 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. Â§312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. Â The drug candidate can be administered to patients as a single agent or in combination with other investigational or marketed agents.1.81â€œPhase 1/2 Studyâ€ means a clinical study of a drug candidate in diseased human patients that satisfies the requirements of a Phase 1 Study and a Phase 2 Study.1.82â€œPhase 2 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. Â§312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States, including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. Â§312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. Â§312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Clinical Study (e.g., a Phase 1/2 Study). Â The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.83â€œPhase 3 Studyâ€ means a clinical study of a drug candidate in human patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. Â The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.84â€œPHS Actâ€ means the United States Public Health Service Act, as amended.1.85â€œPricing and Reimbursement Approvalâ€

means, in a country or other jurisdiction where the Governmental Bodies of such country or jurisdiction approve or determine the price that can be charged for a pharmaceutical or biological product in such country or jurisdiction, or that can be reimbursed by Governmental Bodies for such product in such country or jurisdiction, (a) the approval, agreement, determination, or decision by the relevant Governmental Bodies establishing the price that can be legally charged to consumers for such product in such country or jurisdiction, or (b) the approval, agreement, determination, or decision by the relevant Governmental Bodies establishing the level of reimbursement that will be reimbursed by Governmental Bodies for such product in such country or jurisdiction.1.86â€œProgram Regulatory Materialsâ€ means any and all Regulatory Materials specific to the Licensed Products that are Controlled by Gemma or any of its Affiliates on or after the Effective Date (including, without limitation, the Regulatory Materials transferred from 11â€‹â€‹â€‹Passage to Gemma pursuant to the Transition Services Agreement).1.87â€œProgress Reportâ€ has the meaning set forth in Section 6.8.1.1.88â€œProsecute and Maintainâ€ means activities directed to (a) preparing, filing, prosecuting and maintaining Patent Rights, (b) managing and settling any interference, opposition, re-issue, reexamination, supplemental examination, invalidation (including inter partes or post-grant review proceedings), revocation, nullification or cancellation proceeding relating to the foregoing, but excluding managing and settling the defense of challenges to Patent Rights in a declaratory judgment action or as part a counterclaim in an infringement proceeding.1.89â€œRare Pediatric Disease Priority Review Voucherâ€ or â€œPRVâ€ means a voucher issued by the United States Secretary of Health and Human Services to the sponsor of a rare pediatric disease product application at the time of a marketing approval application, which entitles the holder of the voucher to designate a single human drug application submitted under Section 505(b)(1) of the FD&C Act or Section 351(a) of the PHS Act as qualifying for a priority review, as further defined in 21 U.S.C. 360ff or any subsequent or superseding statute conferring similar rights.1.90â€œRegulatory Approvalâ€ means, with respect to a pharmaceutical or biological product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use, marketing, and sale of such pharmaceutical or biological product in such jurisdiction in accordance with Laws. Â â€œRegulatory Approvalâ€ does not include authorization by a Regulatory Authority to conduct named patient, compassionate use, or other similar activities.1.91â€œRegulatory Authorityâ€ means any Governmental Body, including the FDA, or EMA, or any successor agency thereto, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical or biological product in any country.1.92â€œRegulatory Exclusivityâ€ means, with respect to a given pharmaceutical or biological product and a given country or other jurisdiction, a period of exclusivity (other than exclusivity due to Patent Rights) granted or afforded under Law or by a Regulatory Authority in such country or other jurisdiction that prevents the Regulatory Approval or marketing of any Generic Product of such product in such country, such as new chemical entity, orphan drug or pediatric exclusivity granted or afforded pursuant to the FD&C Act. 1.93â€œRegulatory Materialsâ€ means all (a) applications (including all INDs, MAAs and applications for Pricing and Reimbursement Approval), registrations, licenses, authorizations and approvals (including Regulatory Approvals and Pricing and Reimbursement Approvals), (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files, (c) supplements or changes to any of the foregoing, and (d) clinical and other data, including Clinical Study data, contained or relied upon in any of the foregoing.12â€‹â€‹â€‹1.94â€œRegulatory Submissionsâ€ means all Regulatory Materials submitted to a Regulatory Authority in support of the Development, Manufacture or Commercialization of a pharmaceutical or biological product.1.95â€œResearch Programâ€ means the development program for Licensed Products in and for the Indication in the Field of Use to be conducted by Gemma hereunder in accordance with the applicable development plan therefor.1.96â€œRoyaltyâ€ has the meaning set forth in Section 5.4.1.1.97â€œRoyalty Termâ€ means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period beginning on the First Commercial Sale of such Licensed Product in such country and continuing until the latest of: (a) the expiration of the last Valid Claim of the last Licensed UPenn Patent that Covers such Licensed Product in such country, (b) ten (10) years after the First Commercial Sale of such Licensed Product in such country, and (c) termination or expiration of all Regulatory Exclusivities for such Licensed Product in such country.1.98â€œSaleâ€ means any transaction for which consideration is received or invoiced by Gemma, its Affiliates or Sublicensees for sale, use, lease, transfer, or other disposition of a Licensed Product to or for the benefit of a Third Party. Â For clarity, sale, use, lease, transfer, or other disposition of a Licensed Product by Gemma or any of its Affiliates or Sublicensees to another of these entities for resale (or other disposition) by such entity to a Third Party shall not be deemed a Sale.1.99â€œSales Milestone Eventâ€ has the meaning set forth in Section 5.3. 1.100â€œSales Milestone Paymentâ€ has the meaning set forth in Section 5.3.1.101â€œSDR Reportâ€ has the meaning set forth in Section 2.3.2.1.102â€œSecurities Regulationâ€ has the meaning set forth in Section 7.5.2.1.103â€œSecurities Regulatorâ€ has the meaning set forth in Section 7.5.2.1.104â€œSegregateâ€ means, with respect to a Competing Product, to use reasonable efforts to segregate the Development, Manufacturing and Commercialization of the Competing Product from the Development, Manufacturing and Commercialization of a Licensed Product, including [*]; provided that applicable personnel within a Partyâ€™s (or its Affiliatesâ€™) financial functions may review financial information with respect to the Competing Product as necessary to comply with its financial oversight and reporting obligations.1.105â€œSpecified Obligationsâ€ means the licenses, options, and obligations that Passage or Penn has granted or owes to a Third Party that are identified in Exhibit A, [*].1.106â€œSubcontractorâ€ has the meaning set forth in Section 2.4.1.107â€œSublicense Documentsâ€ means any and all agreements, amendments or written understandings entered into with a Sublicensee (including any of its Affiliates) that are directly or 13â€‹â€‹â€‹indirectly related to a Sublicense, Passage Technology, or Licensed Product. Â For clarity, a development agreement or distribution agreement for a Licensed Product is a Sublicense Document.1.108â€œSublicenseeâ€ means a Person (including any Affiliate) to which a Sublicense, including sub-Sublicensees, is granted pursuant to the terms of Section 2.3.1.1.109â€œTaxâ€ means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body.1.110â€œTermâ€ has the meaning set forth in Section 11.1.1.111â€œTerritoryâ€ means worldwide.1.112â€œThird Partyâ€ means any Person, other than a Party or an Affiliate of a Party.1.113â€œThird Party Claimâ€ has the meaning set forth in Section 10.1.1.1.114â€œThird Party Infringement Claimâ€ has the meaning set forth in Section 8.7.1.1.115â€œTransition Services Agreementâ€ means that certain transition services agreement to be executed by the Parties as of the Effective Date.1.116â€œUnited Statesâ€ or â€œUSâ€ means the United States of America, its territories and possessions.1.117â€œUPenn Agreementâ€ has the meaning set forth in the recitals.1.118â€œUPenn Letter Agreementsâ€ means (a) that certain letter agreement between Passage and Penn dated [*], and (b) that certain letter agreement between Passage and Penn dated [*].1.119â€œUPenn Patentsâ€ means all Patent Rights Controlled by Passage or any of its Affiliates that have been licensed to Passage under the UPenn Agreement and that are related to the Indication. Â The UPenn Patents existing as of the Effective Date are listed on Schedule 1.119 hereto.1.120â€œUPenn Know-Howâ€ means all Know-How Controlled by Passage or any of its Affiliates that have been licensed to Passage under the UPenn Agreement and that is related to the Indication. Â 1.121â€œUS Bankruptcy Codeâ€ has the meaning set forth in Section 11.4.2. 1.122â€œUSD,â€ â€œDollars,â€ or â€œ$â€ means United States dollars.1.123â€œValid Claimâ€ means, with respect to Patent Rights, a claim of (a) an issued and unexpired patent in such Patent Rights which claim has not been revoked or held unenforceable or 14â€‹â€‹â€‹invalid by a decision of a court or governmental agency of competent jurisdiction from which no further appeal can be taken or has been taken within the time allowed for appeal, and has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer; or (b) a pending patent application (that has been pending for no more than [*] from the filing date of such application) that is included in such Patent Rights which was filed and is being prosecuted in good faith, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.Article 2â€‹LICENSE2.1Exclusive License to Gemma. Â Subject to the terms and conditions of this Agreement, during the Term, Passage, on behalf of itself and its Affiliates, hereby grants to Gemma an exclusive (even as to Passage and its Affiliates), transferable (solely in accordance with SectionÂ 12.1), sublicensable (solely in accordance with SectionÂ 2.3), royalty-bearing license under the Passage Technology to make, have made, use, sell, offer for sale and import the Licensed Products for the Indication in the Field of Use in the Territory; provided that, to the extent any Passage Technology is non-exclusively licensed to Passage by Penn (â€œNon-Exclusively Licensed Penn IPâ€), the license granted by Passage to Gemma under such Non-Exclusively Licensed Penn IP shall be exclusive solely with respect to Passageâ€™s interest in such Non-Exclusively Licensed Penn IP (the â€œLicenseâ€).2.2Retained Rights. Â Notwithstanding the exclusive nature of the License, Passage retains the rights to practice the Passage Technology solely to perform its obligations under this Agreement and the UPenn Agreement.2.3Right to Sublicense.2.3.1Passage grants to Gemma the right to grant sublicenses, in whole or in part, under the License (each, a â€œSublicenseâ€) subject to the terms and conditions of this Agreement and specifically this Section 2.3. Â The term â€œSublicenseâ€ shall include any grant of rights under the License by a Sublicensee to any downstream Third Party, provided such downstream Third Party shall also be considered a Sublicensee for purposes of this Agreement.2.3.2All Sublicenses will (a) be issued in writing, (b) to the extent applicable, include all of the rights of Passage and require the performance of obligations due to Passage (and, if applicable, Penn and the U.S. Government under 35 U.S.C. Â§Â§200-212) contained in this Agreement, and (c) include no less than the following terms and conditions:(a)Reasonable record keeping, audit and reporting obligations sufficient to enable Gemma and Passage to reasonably verify the payments due to Gemma, Penn and Passage under such Sublicense and to reasonably monitor such Sublicenseeâ€™s progress in Developing or Commercializing Licensed Product; provided that such obligations shall be no less stringent that those provided in this Agreement for Gemma.(b)Infringement and enforcement provisions that do not conflict with the restrictions and procedural requirements imposed on Gemma and do not provide greater rights to Sublicensee than as provided in Section 8.6.15â€‹â€‹â€‹(c)Confidentiality provisions with respect to Confidential Information of Passage and Penn consistent with the restrictions on Gemma in Article 7 of this Agreement.(d)Covenants by Sublicensee that are equivalent to those made by Gemma in Sections 9.3 and 9.5.(e)A requirement of indemnification of Passage and Penn by Sublicensee that is equivalent to the indemnification of Passage by Gemma under Sections 10.1.1 and 10.1.2 of this Agreement and of Penn by Gemma under Section 10.1.3 of this Agreement.(f)A requirement of obtaining and maintaining insurance by Sublicensee that is equivalent to the insurance requirements of Gemma under Section 10.4 of this Agreement, including coverage under such insurance of Passage and Penn as provided in Section 10.4.(g)Restriction on use of Passageâ€™s and Pennâ€™s names, etc. consistent with Section 7.6 of this Agreement.(h)A requirement of antidiscrimination by Sublicensee no less stringent than that provided in Section 12.3 of this Agreement.(i)A requirement that Passage and Penn are third party beneficiaries of such Sublicense.Any Sublicense that does not include all of the terms and conditions set forth in this Section 2.3.2 or which is not issued in accordance with the terms and conditions set forth in this Section 2.3, shall be considered null and void with no further notice from Passage unless separately approved by Passage in writing.Within [*] after the execution of a Sublicense Document, Gemma shall provide a complete and accurate copy of such Sublicense Document to Passage, in the English Language. Â Passageâ€™s receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Passage or obligation of Gemma under this Agreement.Gemma and its Sublicensees shall provide an annual Sublicense Development Report on or before [*] of each year during the Term (â€œSDR Reportâ€), a form of which is attached hereto as Exhibit B.2.4Right to Subcontract. Â Each Party may subcontract the performance of any of its obligations under this Agreement to one or more Third Party subcontractors engaged for the purpose of Development, Manufacture or Commercialization of the Licensed Products as set forth herein (each such Third Party a â€œSubcontractorâ€). Â All suchÂ SubcontractorsÂ shall be subject to a written agreement that is consistent with the applicable terms and conditions of this Agreement and must meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity, including entering into such Partyâ€™s standard nondisclosure agreement consistent with Article 7 and the ownership and management of intellectual property rights. Â Each Party shall remain responsible and liable to the other Party for 16â€‹â€‹â€‹the performance of allÂ SubcontractorsÂ to the same extent as if such activities were conducted by such Party. Â Any Party engaging a Subcontractor hereunder will remain responsible and obligated for such activities and will not grant rights to such Subcontractor that interfere with the rights of the other Party under this Agreement.2.5Right of Access and Reference. Â 2.5.1Gemma hereby grants to Passage a right of reference to all Program Regulatory Materials in the Territory solely for [*]. Â 2.5.2Passage hereby grants to Gemma a right of reference to all Regulatory Materials Controlled by Passage or its Affiliates in the Territory solely for the purpose of Gemma, its Affiliates or Sublicensees obtaining or maintaining Regulatory Approvals in the Territory for the Licensed Products in the Field of Use. Â 2.5.3Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 2.5, including providing a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of access and reference.2.6No Implied Licenses. Â Except as expressly set forth in this Agreement, neither Party nor its Affiliates, by virtue of this Agreement, shall acquire any license, right or other interest, whether by implication or otherwise, in or to any Know-How, Patent Rights, Regulatory Materials, Materials or other intellectual property rights owned or controlled by the other Party or its Affiliates.2.7 Upstream License. Â To the extent any Passage Technology licensed to Gemma pursuant to the License includes a sublicense to Patent Rights or Know-How licensed to Passage or its Affiliates under the UPenn Agreement, the Parties acknowledge and agree that such sublicensed Passage Technology is subject to the terms and conditions of the UPenn Agreement. Â Gemma agrees to abide by all terms and conditions of the UPenn Agreement as they relate to Gemma as a Sublicensee under such agreement and notwithstanding anything in this Agreement to the contrary, in the event of any conflict between the terms hereof and the terms of the UPenn Agreement as they relate to Gemma as a Sublicensee under the UPenn Agreement, the terms of the UPenn Agreement shall govern. Â Gemma shall timely take all actions reasonably necessary or requested by Passage, including timely providing to Passage all information reasonably necessary, for Passage to comply with its obligations under the UPenn Agreement. Â Without limiting the foregoing, Gemma shall provide to Passage the information necessary for Passage to comply with any royalty or milestone reporting obligations under the UPenn Agreement. Without limiting Section 5.9, Gemma shall be solely responsible for one hundred percent (100%) of all amounts payable by Passage under the UPenn Agreement on and after the Effective Date (including milestone payments and royalties) incurred as a result of Gemmaâ€™s exercise of its rights under this Agreement.2.7.1Penn Retained Rights. Â Without limiting Section 2.7 and notwithstanding the exclusive nature of the License, Gemma acknowledges and agrees that the License is subject to Pennâ€™s rights under the UPenn Agreement, including:17â€‹â€‹â€‹(a)Pennâ€™s right to (i) conduct educational, research, clinical activities, and patient care activities itself, including, but not limited to sponsored research, and (ii) authorize non-commercial Third Parties to conduct educational, research and clinical activities and patient care activities, all as more fully described in the UPenn Agreement; and(b)any applicable requirement, order, written request, or decree by a Regulatory Authority to Penn to make any Patent Rights, Know-How, or Materials available to a Third Party on a non-exclusive basis.2.7.2U.S. Government Rights. Â Without limiting Section 2.7 and notwithstanding the exclusive nature of the License, Gemma acknowledges and agrees that the License is expressly subject to all applicable provisions of any license to the United States Government executed by Penn and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. Â§Â§200-212, applicable governmental implementing regulations, and U.S. Government sponsored research agreement or other guidelines, including that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States.2.8Third Party Licenses. Â Gemma shall have the right, in its sole discretion, to negotiate and obtain licenses or other rights to Third Party Know-How, Patent Rights or other rights in connection with its Development, Manufacture or Commercialization of the Licensed Products in the Territory, and, if applicable, Section 5.4.2(c) shall apply to any amounts payable to such Third Party with respect to any such license or right. Â Article 3â€‹EXCLUSIVITY3.1Exclusivity. Â During the period of [*] after the Effective Date (the â€œExclusivity Periodâ€), Gemma will not, and will ensure that its Affiliates and Sublicensees do not (a) [*], or (b) [*], in each case (a) and (b), other than Commercialization of the Licensed Products in accordance with the terms of this Agreement.3.2Exception for Change of Control. Â Notwithstanding Section 3.1, if: 3.2.1Gemma or any of its Affiliates acquires any Competing Product or the rights to research, develop, manufacture or commercialize any Competing Product anywhere in the Territory in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction), then such acquisition, and the research, development, manufacture or commercialization of such Competing Product thereafter, shall not constitute a breach of Section 3.1 if Gemma or such Affiliate, as applicable, Divests such Competing Product within [*] after the closing of such acquisition and at all times Segregates such Competing Product prior to such Divestiture; and3.2.2Gemma undergoes a Change of Control and the Acquiror (or its Affiliate) is at the time of the closing of such Change of Control researching, developing, manufacturing or commercializing a Competing Product anywhere in the Territory, then such Change of Control, and the research, development, manufacture or commercialization of such Competing Product by 18â€‹â€‹â€‹such Acquiror or its Affiliate, shall not constitute a breach of Section 3.1 if such Acquiror or its Affiliate Divests such Competing Product within [*] after the closing of such Change

of Control and at all times Segregates such Competing Product prior to such Divestiture.Article 4â€‹GOVERNANCE4.1Alliance Managers. Â Each Party will appoint a representative to act as its alliance manager under this Agreement (each, an â€œAlliance Managerâ€). Â Each Alliance Manager will be responsible for promoting effective communication between the Parties and shall be the primary point of contact between the Parties.4.2Cooperation with UPenn Agreement Committees.4.2.1General. Â During the Term, Gemma shall provide Passage with all reasonable assistance, at Passageâ€™s request, for Passage to respond to any request by Penn or under any committee formed under the UPenn Agreement, including preparing relevant reports and responses, providing access to relevant documents, and other evidence, and making its employees reasonably available during business hours as necessary, in each case at Gemmaâ€™s cost and expense. Â Passage shall use Commercially Reasonable Efforts to seek Gemmaâ€™s comments with respect to any such request (including to the extent permissible, seeking a representative of Gemmaâ€™s attendance at any such committee meeting and discussing in good faith any materials submitted thereto with respect to the Licensed Products).4.2.2Updates to Existing JSCs. Â Without limiting Section 4.2.1, during the Term, upon Passageâ€™s reasonable request, Gemma shall provide an update to the development plan delivered under Section 6.1 for the Licensed Products describing the status of the clinical development thereof, for Passageâ€™s and Pennâ€™s review.Article 5â€‹PAYMENTS5.1Product Supply for Clinical Studies. As partial consideration for the License and other rights granted by Passage to Gemma herein, and in exchange for Passageâ€™s supply of product for the conduct of Clinical Studies for the Licensed Products by Gemma or its designee, Gemma shall pay to Passage a one-time, non-refundable, non-creditable product purchase fee of $10,000,000, of which (a) fifty percent (50%) shall be paid to Passage within ten (10) days after the Effective Date, and (b) the other fifty percent (50%) shall be paid to Passage on or before December 15, 2024.5.2Development and Regulatory Milestones. Â Upon the first achievement by Gemma, its Affiliate or a Sublicensee of each development and regulatory milestone event set forth in the table below (each a â€œDevelopment Milestone Eventâ€), Gemma shall make the corresponding one-time, non-refundable, non-creditable payment set forth in the table below (each a â€œDevelopment Milestone Paymentâ€) to Passage in accordance with Section 5.6.1.Development Milestone EventDevelopment Milestone Payment (USD)19â€‹â€‹[*][*][*]Total[*]If any of the above Development Milestone Events are skipped (such that a later Development Milestone Payment becomes due and payable before an earlier Development Milestone Payment), then the skipped Development Milestone Event(s) will be deemed to have been achieved upon the achievement of the subsequent Development Milestone Event, and the Development Milestone Payment(s) corresponding to such skipped Development Milestone Event(s) shall be due and payable at the same time as the subsequent Development Milestone Event.5.3Sales Milestones. Â Upon the first achievement of each sales-based milestone event set forth in the table below (each, a â€œSales Milestone Eventâ€), Gemma shall make the corresponding one-time, non-refundable, non-creditable payment set forth in the table below (each a â€œSales Milestone Paymentâ€) to Passage in accordance with Section 5.6.1.Sales Milestone EventSales Milestone Payment (USD)[*][*][*][*][*][*]Total[*]Each of the foregoing Sales Milestone Payments in this Section 5.3 shall be payable a maximum of one (1) time hereunder regardless of the number of times the applicable Sales Milestone Event is achieved. Â For the avoidance of doubt, the aggregate maximum amount payable by Gemma under this Agreement pursuant to this Section 5.3 is [*]. Â In the event that in a given Calendar Year more than one (1) Sales Milestone Event is achieved, Gemma shall pay to Passage the Sales Milestone Payment with respect to each such Sales Milestone Event.5.4Royalty Payments. 5.4.1Royalty Payments for Licensed Products. Â Subject to the remainder of this Section 5.4, on a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product, Gemma shall pay Passage a [*] royalty on aggregate annual Net Sales of such Licensed Product in the Territory (the â€œRoyaltyâ€), calculated by multiplying [*] by the aggregate annual Net Sales of all Licensed Products in the Territory. Â Such payments, and associated reports, shall be made in accordance with Section 5.6.2.5.4.2Royalty Reductions.(a)No Valid Claim. On a country-by-country basis, if at any time during the Royalty Term for a Licensed Product in such country there is no Valid Claim of the Licensed UPenn Patents that Covers such Licensed Product in such country and such Licensed 20â€‹â€‹â€‹Product is not subject to Regulatory Exclusivity, then (i) the royalty rate set forth in Section 5.4.1 for such Licensed Product shall be permanently reduced in such country by [*] for the remainder of such Royalty Term, and (ii) no Royalty at all will apply to such Licensed Product [*]. Â (b)Compulsory License. Â In the event that Gemma or Passage receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. Â If any Third Party obtains a Compulsory License in any country, then: (i) Gemma or Passage (whoever has first notice) shall promptly notify the other Party; and (ii) beginning as of the date the Third Party obtained such Compulsory License in such country, the Royalty rate payable under Section 5.4.1 to Passage for Net Sales in such country will be adjusted to equal any lower Royalty rate granted to such Third Party for such country with respect to the sales, use, lease, transfer or other disposition of such Licensed Product by such Third Party therein.(c)Third Party Payments. If, after the Effective Date, Gemma determines upon the advice of outside intellectual property counsel that a license to Patent Rights from a Third Party is reasonably necessary to develop, commercialize, or manufacture a Licensed Product in a particular country, Gemma may obtain such Third Party license to such Patent Rights. Â Gemma may deduct from any Royalty payments due to Passage under Section 5.4.1 an amount equal to [*] of any Royalty paid by Gemma to a Third Party on Sales of a particular Licensed Product in a particular country during a Calendar Quarter under a Third Party license obtained by Gemma for such country, pursuant to this Section 5.4.2(b).(d)Generic Product. In the event that one or more Generic Product(s) with respect to a particular Licensed Product enter(s) the market in a particular country, and such Generic Product(s) in the aggregate have a market share of [*] or more in that country, Gemma may reduce the Royalty payments for Sales of such Licensed Product in such country by [*]; provided that if Gemma reduces the Royalty payments under this Section 5.4.2(d), Gemma shall resume making Royalty payments without reduction under this Section 5.4.2(d) as of the earlier of (a) no Generic Product being sold for at least [*] in such country, and (b) a court of competent jurisdiction determines that a Valid Claim of a Licensed UPenn Patent is valid and infringed by such Generic Product in such country.(e)Cumulative Reductions Floor. In no event will the amount of Royalties due to Passage for a Licensed Product in any given Calendar Quarter be reduced as a result of the reductions set forth in Sections 5.4.2(c) and 5.4.2(d) (cumulatively) by more than [*] of the amount that otherwise would have been due and payable to Passage in such Calendar Quarter for such Licensed Product.5.4.3Royalty Payments. Â Gemma shall pay Royalties owed to Passage on a Calendar Quarter basis on or before the following dates:(a)[*] for any Sales that took place in the Calendar Quarter ending December 31, of the prior Calendar Year;(b)[*] for any Sales that took place in the Calendar Quarter ending March 31 of such Calendar Year;21â€‹â€‹â€‹(c)[*] for any Sales that took place in the Calendar Quarter ending June 30 of such Calendar Year; and(d)[*] for any Sales that took place in the Calendar Quarter ending September 30 of such Calendar Year.5.5FDA Priority Review Voucher. Â In the event Gemma or its Affiliate or Sublicensee receives a Rare Pediatric Disease Priority Review Voucher based on a Regulatory Approval of a Licensed Product, then Gemma shall promptly provide written confirmation to Passage that it or its Affiliate or Sublicensee received such PRV. Â In addition, if and when the conditions of either 5.5.1 or 5.5.2 are met, Gemma shall pay Passage the amounts set forth in either 5.5.1 or 5.5.2, as applicable:5.5.1In the event Gemma or its Affiliate or Sublicensee sells the PRV to a Third Party, then Gemma will pay to Passage [*] of all consideration, including fees, minimum royalties, milestone payments or other payments Gemma or its Affiliate or Sublicensee receives for the sale of the PRV within [*] after receipt of such consideration. Â If Gemma or its Affiliate or Sublicensee receives consideration other than cash, Gemma and Passage will cooperate in good faith to perform a valuation of the non-cash consideration portion received in exchange for the PRV and such valuation shall be deemed to be the fair value thereof for calculating the fee for the non-cash consideration portion to be paid to Passage. Â Gemma agrees to provide to Passage under terms of confidentiality the executed documentation related to the transaction resulting in the non-cash consideration, including all terms without redaction that are necessary for Passage, by itself or through an auditor reasonably acceptable to Gemma, to perform a valuation of the non-cash consideration.5.5.2In the event Gemma or its Affiliate or Sublicensee uses the PRV for a Gemma product or Gemmaâ€™s Affiliateâ€™s or Sublicenseeâ€™s product, then Gemma will pay to Passage [*] of the fair market value of such PRV within [*] after such use. Â The Parties will meet at a mutually agreeable time (no later than [*] after the use of such PRV) and place to present such evidence as either Party desires in an effort to mutually and in good faith attempt to arrive at a mutually acceptable fair market value for the PRV. Â If the Parties have not agreed on the fair market value for the PRV within [*] of such request, then upon either Partyâ€™s written request, the Parties will have the matter resolved by an impartial industry expert reasonably acceptable to both Parties to decide the fair market value for the PRV using a â€œbaseball arbitrationâ€ procedure, where each Party shares with the decision-maker, and with one another, its final proposal for the fair market value for the PRV, and the decision-maker selects one Partyâ€™s proposal or the otherâ€™s without modification. Â Each Party shall bear its own costs with respect to such arbitration (including its reasonable legal fees).5.6Payment Terms.5.6.1Milestone Payments. Â Gemma shall promptly notify Passage in writing upon the occurrence of a Development Milestone Event or Sales Milestone Event and Gemma shall pay Passage in full the corresponding non-refundable Development Milestone Payment or Sales Milestone Payment within [*] after such occurrence.22â€‹â€‹â€‹5.6.2Royalty Reports. Â Within [*] after the end of each Calendar Quarter, Gemma shall deliver to Passage (or at Passageâ€™s written direction, Penn) a report (â€œFinancial Reportâ€) setting out all details necessary to calculate the Royalty due under this Article 5 for such Calendar Quarter, including:(a)[*];(b)Gross sales and Net Sales of each Licensed Product made by Gemma, its Affiliates and Sublicensees (including sub-Sublicensees);(c)Royalties;(d)The method and currency exchange rates (if any) used to calculate the Royalties;(e)A specification of all deductions and their dollar value that were taken to calculate Net Sales;(f)A list of all countries in which Licensed Product is being manufactured (on a Licensed Product-by-Licensed Product basis); and(g)The date of First Commercial Sale in the United States (this need only be reported in the first Financial Report following such First Commercial Sale in the United States).Each Financial Report shall be in the form of the sample report attached hereto as Exhibit C.5.7Payment Currency; Exchange Rate; Offset. Â All payments to be made under this Agreement shall be made in USD. Â Payments to a Party shall be made by electronic wire transfer of immediately available funds to the account of the other Party, as designated in writing to the paying Party. Â If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the average of the rates quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter for which such payment is made. Â Gemma shall not have the right to offset any payment that is owed by Gemma to Passage but not yet paid against any payments owed by Passage to Gemma under this Agreement. Â 5.8Late Payments. Â Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [*] per month or (b) the maximum rate permitted by Law; in each case calculated on the number of days such payment is delinquent, compounded monthly. Â In the event of a default in payment of any payment owing under the terms of this Agreement, and if it becomes necessary for Passage to undertake legal action to collect said payment, Gemma shall pay reasonable, documented legal fees and costs incurred in connection therewith.5.9Payments to Third Parties. Â Gemma shall be solely responsible for one hundred percent (100%) of all amounts payable by Passage under the UPenn Agreement on and after the Effective Date (including milestone payments and royalties) incurred as a result of Gemmaâ€™s 23â€‹â€‹â€‹exercise of its rights under this Agreement. Â Gemma shall pay such amounts to Passage in accordance with this Article 5 (unless otherwise directed by Passage in writing to make payments directly to such licensor), in each case, no later than [*] prior to the date on which the applicable amount is due and payable by Passage under the UPenn Agreement. Â Without limiting the foregoing, Gemma shall promptly (but in any event not more than [*] thereafter) provide notice to Passage upon the achievement (by Gemma, its Affiliates or Sublicensees) of any of the third party milestones set forth in Exhibit D and pay the corresponding milestone amount owed under the UPenn Agreement, as provided by Passage to Gemma, to Passage (unless otherwise directed by Passage in writing to make payments directly to Penn) no later than [*] following the achievement of such milestone. Â At the request of Gemma, Passage shall use Commercially Reasonable Efforts to seek applicable and available reductions of any royalties owed under the UPenn Agreement.5.10Accounting. Â Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.5.11Records and Audit Rights.5.11.1Records. Â Gemma will keep accurate books and records of all Licensed Products developed, manufactured, used, or sold and all Sublicenses, collaboration agreements and joint venture agreements entered into by Gemma that involve Passage Technology. Â Gemma will preserve these books and records for at least [*] from the date of the Financial Report to which they pertain. Â Upon reasonable notice, key personnel, books, and records will be made reasonably available and will be open to examination by representatives or agents of Passage or Penn during regular office hours to determine their accuracy and assess Gemmaâ€™s compliance with the terms of this Agreement and the UPenn Agreement; provided that Gemma shall not have an obligation to provide access more than once in any given [*] period to Passage.5.11.2Audit. Â In addition to the right of Passage and Penn to examine the books and records and interview key personnel as provided in Section 5.11.1, Passage or Penn (each an â€œAuditing Partyâ€), at its own cost, through an independent auditor reasonably acceptable to Gemma (and who has executed an appropriate confidentiality agreement reasonably acceptable to Gemma that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to the Auditing Party), may inspect and audit the relevant records of Gemma pertaining to the calculation of any payments due hereunder (including any Development Milestone Payments, Sales Milestone Payments, or Royalties). Â Gemma shall provide such auditors with access to the records during reasonable business hours. Â Such access need not be given to any such set of records more often than once each year for a given Auditing Party or more than [*] after the date of any report to be audited. Â The Auditing Party shall provide Gemma with written notice of its election to inspect and audit the records related to the payments due hereunder not less than [*] prior to the proposed date of review of Gemmaâ€™s records by the Auditing Partyâ€™s auditors. Â Should the auditor find any underpayment by Gemma, Gemma shall (a) promptly pay Passage (or at Passageâ€™s written direction, Penn) the amount of such underpayment; (b) shall reimburse the Auditing Party for the cost of the audit, if such underpayment equals or exceeds the higher of (i) [*] or (ii) [*] of all payments paid to Passage (or with respect to Penn, the amount owed under the UPenn Agreement) during the time period audited; and (c) provide such auditors with an audit right exercisable within [*] after such Auditing Party receives the audit report. Â If the auditor finds overpayment by Gemma, then Gemma shall 24â€‹â€‹â€‹have the right to deduct the overpayment from any future income due to Passage (or with respect to Penn, the amount owed under the UPenn Agreement) or, if no such future payments are due hereunder (or with respect to Penn, future payments due under the UPenn Agreement) shall refund the overpayment to Gemma within [*] after the Auditing Party receives the audit report; provided that to the extent any amounts owed to Gemma relate to the UPenn Agreement, Passage shall refund the overpayment to Gemma within [*] after receiving payment for such overpayment from Penn, if not paid directly to Gemma.5.12Taxes. All payments made by Gemma to Passage (or Passageâ€™s designee) under this Agreement shall be made free and clear of and without any deduction for or on account of any Taxes on or with respect to such payments.5.13Blocked Currency. Â If due to Law in a country or other jurisdiction in the Territory, conversion into USD or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Gemma shall promptly notify Passage and, thereafter, amounts accrued in such country or other jurisdiction under this Article 5 (other than Section 5.9) shall be paid to Passage (or its designee) in such country or other jurisdiction in local currency by deposit in a local bank designated by Passage and to the credit of Passage, unless the Parties otherwise agree. For clarity, [*].Article 6â€‹DEVELOPMENT AND COMMERCIALIZATION6.1Development Plan. Gemma shall provide Passage or its designee with a development plan (or updated development plan) no later than [*] of each year during the Term. Â The development plan shall include a timeline for detailed activities to be conducted by Gemma, its Affiliates and Sublicensees, and Gemma shall provide Passage with [*] progress reports regarding achievements and activities under such development plan. Â Subject to Section 6.2, Gemma will have sole responsibility for and sole decision-making over the Development of the Licensed Products for the Indication in the Field of Use, and will be solely responsible for the associated costs of such Development.6.2Clinical Development. Â Gemma shall have the first right to sponsor all clinical activities and lead regulatory interactions for the Licensed Products, and will be solely responsible for the associated costs of such Development. Â Gemma will consider in good faith using Penn as a study site for one or more Clinical Studies where Penn can reasonably demonstrate that Pennâ€™s capabilities and costs are reasonably comparable to other potential study sites. Â If Penn (in its sole discretion) is willing and able to conduct a Clinical Study for a Licensed Product developed under the Research Program, the Parties and Penn will negotiate a separate clinical trial agreement and 25â€‹â€‹â€‹a separate clinical trial budget prior to initiation of such Clinical Study; provided that any such study shall be at Gemmaâ€™s cost and expense.6.3Commercialization. Gemma will have sole responsibility for and sole decision-making over the Commercialization of the Licensed Products for the Indication in the Field of Use, and will be solely responsible for the associated costs of such Commercialization.6.4Manufacturing. Â Gemma will have sole responsibility for and sole decision-making authority over all Manufacturing of the Licensed Products for the Indication in the Field of Use.6.5Regulatory. Â Gemma will have responsibility for and decision-making over regulatory activities for the Licensed Products for the Indication in the Field of Use. Â Gemma will have the right to conduct all communications with Regulatory Authorities, including all meetings, conferences, and discussions (including advisory committee meetings), with regard to Licensed Products for the Indication in the Field of Use; provided, [*]. Â Gemma will lead and have control over preparing and submitting all Regulatory Submissions related to the Licensed Products for the Indication in the Field of Use, including all MAAs, provided, however, that Gemma shall provide Passage (or at Passageâ€™s written request, Penn) with copies of all such applications prior to submission, to the extent such submission includes any Confidential Information of Passage. Â Gemma will own

any and all Regulatory Materials, Regulatory Submissions (including INDs), and Regulatory Approvals related to the Licensed Products for the Indication in the Field of Use, which will be held in the name of Gemma or its designees. 6.6General Diligence. Gemma will use Commercially Reasonable Efforts to actively Develop, obtain Regulatory Approval for and Commercialize at least one Licensed Product for the Indication in the Field of Use.6.7Diligence Events.6.7.1General. Â Gemma shall achieve each of the diligence events set forth in Exhibit E (each a â€œDiligence Eventâ€) by the corresponding achievement date (each a â€œAchievement Dateâ€). Â Gemma acknowledges that the achievement of each Diligence Event by the corresponding achievement date is a condition of the UPenn Agreement. Â The timeline for each Achievement Date is based on the assumption that Development and Commercialization of the Licensed Products does not encounter material regulatory or other delays for reasons outside of Gemmaâ€™s reasonable control. Â Where such circumstances exist, Passage agrees to negotiate in good faith with Gemma and Penn (on Gemmaâ€™s behalf), upon Gemmaâ€™s written request and provided such request is made at least [*] prior to the Achievement Date for a Diligence Event, an extension of the Achievement Date for a Diligence Event for such Licensed Products as reasonably requested by Gemma. Â If the Parties and Penn have not agreed on a requested extension within [*] of Passageâ€™s notice to Penn of such request, then upon either Gemmaâ€™s or Pennâ€™s written request, Passage and Penn [*]. Â For clarity, [*].6.7.2Review. Â Gemma acknowledges that if, following a review requested by Penn under Section 4.2.2, Penn in good faith reasonably believes that Gemma has not materially funded any activities to advance the Development of the Licensed Products during any [*], Penn 26â€‹â€‹â€‹may submit such matter for arbitration by an arbitrator selected in accordance with Section 6.7.1 to determine whether Gemma has failed to materially fund any such activities. Â The Parties shall use Commercially Reasonable Efforts to cooperate with each other with respect to any such arbitration (including to the extent permissible, seeking a representative of Gemmaâ€™s attendance at any hearing and discussing in good faith any materials submitted thereto with respect to the Licensed Products). Â All costs and expenses incurred by Passage with respect to such arbitration (including its reasonable legal fees) shall be reimbursed by Gemma within [*] of an invoice therefor. Â Gemma acknowledges and agrees that, if (i) the arbitrator finds that Gemma (on behalf of Passage) has failed to materially fund any such activities as set forth above, and (ii) Gemma does not cure such failure to materially fund within [*] of the arbitratorâ€™s determination, then, notwithstanding anything in this Agreement to the contrary, Passage will have the right to terminate this Agreement with immediate effect upon written notice to Gemma.6.8Progress Reports. 6.8.1Prior to the First Commercial Sale of a Licensed Product, on an annual basis but in no event later than [*] of each Calendar Year, Gemma shall submit to Passage (or at Passageâ€™s written direction, Penn) a progress report (each, a â€œProgress Reportâ€) covering Gemmaâ€™s (and any Affiliatesâ€™ and Sublicenseesâ€™) activities related to the Development of all Licensed Products and the obtaining of Regulatory Approvals necessary for Commercialization of Licensed Products. 6.8.2Each Progress Report must include all of the following for each annual period:(a)Summary of material Development activities; (b)Summary of material Commercialization activities; (c)Identification of filings for Regulatory Approval and other material correspondence with Regulatory Authorities; (d)An updated SDR Report listing any and all Sublicenses granted by Gemma; and (e)The names and addresses of all Sublicensees, and a current and valid phone number and e-mail address for a principal point of contact at each such Sublicensee who is responsible for administering the Sublicensee.Article 7â€‹CONFIDENTIALITY7.1Confidential Information. Â For purposes of this Agreement, â€œConfidential Informationâ€ of a Party means any and all confidential or proprietary information, data, or materials, including all Know-How and other scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial and commercial information or data, whether or not patentable and in any form (written, oral, photographic, electronic, magnetic, or otherwise), including information of Third Parties, that such Party (or an Affiliate or representative of such 27â€‹â€‹â€‹Party) discloses or otherwise makes available to the other Party (or to an Affiliate or representative of the other Party) in connection with this Agreement. Â The Passage Technology shall be the Confidential Information of Passage, and the terms and conditions of this Agreement shall be the Confidential Information of both Parties.7.2Duty of Confidence; Exceptions. Â Each Party agrees that, during the Term and for a period of [*] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (including for the exercise of the rights and licenses granted to such Party hereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. Â The foregoing confidentiality and non-use obligations shall not apply with respect to any information that the receiving Party can demonstrate by competent written proof:7.2.1was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed by the disclosing Party to the receiving Party, or was otherwise developed independently by or for the receiving Party without use of or reference to the disclosing Partyâ€™s Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;7.2.2was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party, as evidenced by written records of the receiving Party;7.2.3became generally available to the public or otherwise part of the public domain after its disclosure other than through any act or omission of the receiving Party in breach of this Agreement; or7.2.4was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.Any combination of features shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.7.3Authorized Disclosures. Â Notwithstanding Section 7.2, the receiving Party may disclose the disclosing Partyâ€™s Confidential Information if and to the extent such disclosure is reasonably necessary in the following instances:7.3.1subject to Section 7.5, to comply with Law; 7.3.2to its external attorneys, independent accountants, or financial advisors solely for the purpose of enabling such attorneys, independent accountants, or financial advisors to provide advice to it; and7.3.3to its Affiliates, employees, consultants, and agents and actual or potential Sublicensees (in the case of Gemma), collaborators, actual or potential investors, or contractors, 28â€‹â€‹â€‹as applicable and as may be needed to exercise its rights or perform its obligations in accordance with the terms of this Agreement; provided that in each of the cases of Sections 7.3.1-7.3.3 such Person is subject to a written agreement containing obligations of confidentiality and non-use at least as stringent as those herein (or without such agreement for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement).Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Partyâ€™s Confidential Information pursuant to SectionsÂ 7.3.1 and 7.3.3, it will, except where impracticable, promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Partyâ€™s efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the other Partyâ€™s expense. Â In any such event, each Party agrees to take all reasonable actions to minimize disclosure of the other Partyâ€™s Confidential Information. Â Any information disclosed pursuant to this Section 7.3 shall remain, subject to Section 7.2, the Confidential Information of the disclosing Party and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 7. Â 7.4Prior Confidentiality Agreements. Â This Agreement supersedes that certain Mutual Confidentiality Agreement between the Parties effective as of [*] (the â€œCDAâ€). Â All information exchanged between the Parties under the CDA shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 7.7.5Public Disclosures; Securities Filings.7.5.1Press Release. Â Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed); provided, however, that (a) neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Securities Regulations, (b) either Party may make subsequent public disclosure of the contents of any such approved press release or other public statement, and (c) Passage shall have the right to make public announcements regarding the achievement of any material events regarding the progress of the Development and Commercialization of a Licensed Product under this Agreement, as well as the achievement of Development Milestone Events or Sales Milestone Events, or the receipt of any payments hereunder.7.5.2Securities Filings. Â Notwithstanding anything herein to the contrary, a Party or its Affiliates may disclose the relevant terms of this Agreement to the extent required or advisable to comply with the rules and regulations promulgated by the US Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory (such rules and regulations â€œSecurities Regulationsâ€ and each such agency a â€œSecurities Regulatorâ€). Â If a Party is required by Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator, such Party agrees to reasonably consult and 29â€‹â€‹â€‹coordinate with the other Party with respect to such disclosure and, if applicable, the preparation and submission of a confidential treatment request for this Agreement. Â Notwithstanding the foregoing, if a Party is required by Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator and such Party has (i) promptly notified the other Party in writing of such requirement and any respective timing constraints, (ii) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure, and (iii) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Law or the applicable Securities Regulator. Â If a Party seeks to make a disclosure or filing as set forth in this Section 7.5.2 and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will reasonably consider such comments and use good faith efforts to incorporate such comments in the disclosure or filing; provided that prior to making any such filing of this Agreement, the Parties shall reasonably cooperate and use good faith efforts to agree on a redacted form of this Agreement to be so filed.7.6Use of Names. Â Gemma, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Passage, Penn or any Penn school, organization, employee, student or representative, without the prior written consent of Passage or Penn, as applicable. Â Notwithstanding the foregoing, Gemma may use the name of Passage or Penn in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by Gemma for the purpose of raising financing for the operations of Gemma as related to Licensed Product, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Passage Technology (subject to the provisions of Article 7) have been licensed by Gemma from Passage and sublicensed by Gemma from Penn, and/or to inform a reader of the identity and published credentials of inventors of intellectual property, and (b) any securities reports required to be filed with a Securities Regulator in the US.Article 8â€‹INTELLECTUAL PROPERTY8.1Ownership. Â Inventorship of Arising Know-How and all intellectual property rights therein shall be determined in accordance with principles of inventorship for Patent Rights and other intellectual property under US law, and ownership shall follow inventorship. Â 8.2Patent Prosecution and Maintenance. Â 8.2.1Licensed UPenn Patents. Â Gemma acknowledges that the Prosecution and Maintenance of the Licensed UPenn Patents shall be controlled by Penn. Â Passage shall use Commercially Reasonable Efforts to cooperate with Gemma to provide any comments to such Prosecution and Maintenance of the Licensed UPenn Patents to Penn, as allowable under the UPenn Agreement. Â Gemma will bear all amounts required to be paid to Penn under the UPenn Agreement during the Term for the Prosecution and Maintenance of the Licensed UPenn Patents.30â€‹â€‹â€‹8.2.2Gemma Collaboration Patents. Â As between the Parties, Gemma shall have the sole right, but not the obligation, to Prosecute and Maintain the Gemma Collaboration Patents in the Territory, at Gemmaâ€™s cost and expense.8.3Cooperation for Patent Extensions. Â [*].8.4Patent Listings. Â Passage shall have the sole right to list or de-list the UPenn Patents in the FDAâ€™s â€œPurple Bookâ€ or any equivalent thereto in any country in the Territory with respect to the Licensed Products. Â Gemma shall reasonably cooperate with Passage in making or withdrawing any such listing for a UPenn Patent, including executing all necessary documents to implement such patent listing, at its cost and expense. Â 8.5Common Interest Disclosures. Â With regard to any information or opinions exchanged pursuant to this Agreement by the Parties (or their Affiliates) regarding intellectual property owned by Third Parties, the Parties agree that they have a common legal interest in coordinating Prosecution and Maintenance of their respective Patent Rights, as set forth in this Article 8, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Development, Manufacturing or Commercialization of the Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the Development, Manufacturing or Commercialization of the Licensed Products. Â Accordingly, Gemma and Passage agree that all such information and materials obtained by Gemma or Passage from each other will be used solely for purposes of the Partiesâ€™ common legal interests with respect to the conduct of this Agreement. Â All information and materials will be treated as protected by the attorney-client privilege, the work product privilege and any other privilege or immunity that may otherwise be applicable. Â By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Â Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Partyâ€™s prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Party.8.6Patent Enforcement. 8.6.1Notice. Â Each Party shall notify the other within [*] after becoming aware of any alleged or threatened infringement by a Third Party of any UPenn Patent or Gemma Collaboration Patent (an â€œInfringement Noticeâ€), which infringement adversely affects or could reasonably be expected to adversely affect the Development, Manufacture or Commercialization of any Licensed Product for the Indication in the Field of Use in the Territory, or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Right (each a â€œCompetitive Infringementâ€). Â 8.6.2Gemma Collaboration Patents. Â As between the Parties, Gemma shall have the sole right, but not the obligation, to enforce the Gemma Collaboration Patents or take any steps to abate an alleged or actual Third Party infringement of any Gemma Collaboration Patent anywhere in the Territory, at Gemmaâ€™s sole cost and expense.31â€‹â€‹â€‹8.6.3Licensed UPenn Patents. (a)Notification of Infringement. Â Gemma [*] without first obtaining the written consent of Passage, which consent will not be unreasonably withheld, conditioned or delayed. Â If Gemma [*], then Gemmaâ€™s right to request Passage initiate an Enforcement Action under Section 8.6.3(b) below will terminate immediately without the obligation of Passage to provide notice to Gemma. Â Passage and Gemma will use their diligent efforts to cooperate with each other and Penn to terminate such infringement without litigation.(b)Request for Enforcement. Â If the Competitive Infringement of a UPenn Patent has not been abated within [*] following the date the Infringement Notice was provided and during the period in which, and in the jurisdiction where, Passage is exclusively licensed under such infringed UPenn Patent (such UPenn Patent, during such period and in such jurisdiction, the â€œExclusive Penn Patent Rightsâ€), then Gemma may, but no later than [*] following the date of the Infringement Notice, request Passage to institute an Enforcement Action of an Exclusive Penn Patent Right against the infringer. Â Following receipt of such request, Passage shall [*]. Â Passage shall keep Gemma reasonably informed as to the status of any such Enforcement Action and shall consider in good faith the comments of Gemma with respect thereto. Â Gemma acknowledges that Passage or Penn may bring an action with respect to any such Competitive Infringement if not requested by Gemma within such [*] period following the date of the Infringement Notice.(c)Cooperation. Â In connection with any Enforcement Action under this Section 8.6.3, Gemma shall [*]. Â Gemma shall be entitled to separate representation in an Enforcement Action by counsel of its own choice and at its own cost and expense, but Gemma shall at all times cooperate fully with Passage.8.6.4Biosimilar Action. Â Notwithstanding anything to the contrary in Section 8.6.1, during the Term, each Party shall [*] give written notice to the other Party of any application for [*] (each a â€œBiosimilar Actionâ€) of which it becomes aware and referencing [*]. Â Passage shall have the sole and exclusive right, but not the obligation, to prosecute and manage any litigation with respect to any Biosimilar Action at its cost and expense, and Gemma shall cooperate fully in any such action at Passageâ€™s cost and expense.8.6.5Recoveries. Â Unless otherwise agreed to by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.6.3, or Section 8.6.4 (whether by way of settlement or otherwise) shall [*] with respect to such action ([*]), and any remaining recovery amount shall [*], provided [*]. Â Unless otherwise agreed by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.6.2 shall [*].8.7Infringement of Third Party Rights.8.7.1Notice. Â Each Party shall promptly notify the other Party in writing within [*] after receiving a notice of a claim or assertion that any Licensed Product, or any Passage Technology, infringes or misappropriates any Third Partyâ€™s Patent Rights or other intellectual property rights in any country (â€œThird Party Infringement Claimâ€), which notice shall include a copy of any summons or complaint (or the equivalent thereof), including, if applicable, a certified 32â€‹â€‹â€‹translation into English, received regarding the foregoing. Â Thereafter, the Parties shall promptly meet to consider the Third Party Infringement Claim and the appropriate course of action and may, if appropriate, agree on and enter into a â€œjoint defense agreementâ€ wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Â The Parties shall assert and not waive the joint defense privilege, attorney work-product doctrine, attorney client privileges or any other privileges or protections that may apply with respect to any communications between the Parties in connection with the defense of such claim or assertion.8.7.2Defense. Â Unless the alleged infringing Party seeks indemnification for a Third Party Infringement Claim pursuant to Section 10.1 or Section 10.2, as between the Parties, the alleged infringing Party [*]. Â Neither Party shall enter into any settlement of any such Third Party claim that materially adversely

affects the other Partyâ€™s rights or interests under this Agreement or imposes any obligation or liability on the other Party without the other Partyâ€™s prior written consent (or with respect to Gemma, that materially adversely affects Pennâ€™s rights or interests in the Licensed UPenn Patents or imposes any obligation or liability on Penn without Passageâ€™s prior written consent).8.8Patent Marking. Â Gemma shall mark all Licensed Products in accordance with applicable patent marking laws and shall require all of its Affiliates and Sublicensees to do the same.8.9Trademarks. Â Gemma will solely own all right, title and interest in and to any trademarks adopted for use with the Licensed Products for the Indication in the Field of Use in the Territory, and will be responsible for the registration, filing, maintenance and enforcement thereof. Â Neither Passage nor any of its Affiliates will at any time do or authorize to be done any act or thing which is likely to materially impair the rights of Gemma therein, and will not at any time claim any right of interest in or to such marks or the registrations or applications therefor. Â Neither Passage nor any of its Affiliates will use Gemmaâ€™s or any of its Affiliatesâ€™ trademarks or any trademark that is confusingly similar thereto. Article 9â€‹REPRESENTATIONS, WARRANTIES, AND COVENANTS9.1Representations and Warranties of Each Party. Â Each Party represents and warrants to the other as of the Effective Date that:9.1.1such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;9.1.2such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;9.1.3this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditorsâ€™ rights generally and by general equitable principles; and33â€‹â€‹â€‹9.1.4such Party has all right, power and authority to enter into this Agreement and to perform its obligations under this Agreement.9.2Representations and Warranties of Passage. Â Passage represents and warrants to Gemma as of the Effective Date that: 9.2.1it Controls all of the Licensed UPenn Patents;9.2.2it has received no written notice or allegation, and has no other reasonable basis to believe, that any of the Licensed UPenn Patents are invalid or unenforceable, or that the use, development, practicing or exploitation of any Licensed UPenn Patents infringes the Patent Rights of any Third Party (provided, for clarity, that this Section 9.2.2 will not be construed as requiring Passage to discover, or to conduct any investigation regarding, the Patent Rights of any Third Party of which Passage has no actual knowledge and with respect to which it has not received any written notice or allegation);9.2.3it has not granted any license or option rights nor made any contractual commitments that are inconsistent with the rights granted to Gemma hereunder;9.2.4to the knowledge of Passage, the License includes all available Patent Rights Controlled by Passage that are necessary for the Development, Manufacture and Commercialization of the Licensed Products for the Indication in the Field of Use in the Territory.9.3Mutual Covenants. Â Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, such Party shall, and shall cause its Affiliates, Sublicensees and subcontractors to, comply with Law, including, as applicable, cGMP, cGLP and cGCP. Â Without limiting the foregoing, the Parties additionally agree as follows:9.3.1Data Privacy. Â Each Party shall: (a) comply with Law in relation to data protection, privacy, or restrictions on, or requirements in respect of, the processing of Personal Data of any kind, including the Health Insurance Portability and Accountability Act, General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR), and any equivalent Law in any other jurisdiction (as any of the foregoing may be amended from time to time, collectively, â€œData Protection Lawsâ€) with respect to the collection, use, transfer, storage, destruction, aggregation or other use of subject health information or other Personal Data (as defined in the applicable Data Protection Laws, collectively, â€œPersonal Dataâ€) in connection with its activities under or in connection with this Agreement, including the Development and Commercialization of any Licensed Product hereunder; (b) implement appropriate and reasonable security processes and controls in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of Personal Data in accordance with Data Protection Laws; and (c) take such steps as necessary to comply with Data Protection Laws to permit such Party to disclose Personal Data to the other Party and to permit the other Party to use and disclose such Personal Data for its own purposes in accordance with this Agreement. Â Without limiting the foregoing, if required by Law, the Parties will negotiate and enter into a written agreement with respect to the collection, storage, transfer, processing and use of Personal Data by the Parties and their Affiliates as contemplated by this Agreement.34â€‹â€‹â€‹9.3.2No Debarment or Regulatory Sanction. Â Neither Party shall employ (or, knowingly use any contractor, subcontractor, distributor or other Person that provides services to such Party in connection with this Agreement that employs) any Person that is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority (including, as applicable, the FDA pursuant to its authority under Sections 306(a)Â andÂ (b) of the FD&C Act) or that is the subject of any investigation or proceeding which may result in debarment, disqualification, blacklisting, banning or any similar sanction by any applicable Regulatory Authority, in each case, in connection with the performance of its activities under this Agreement. Â Each Party shall notify the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority or becomes the subject of any such investigation or proceeding. 9.4Passage Covenants. Â Passage hereby covenants to Gemma during the Term that (a) it shall, and shall cause its Affiliates to, remain in compliance in all material respects with the UPenn Agreement, and it shall promptly provide to Gemma any written notice received from or provided to the counterparty to the UPenn Agreement that relates to Gemmaâ€™s rights or obligations hereunder, including any notice of breach or default, and (b) it will not (and will cause its Affiliates not to), without Gemmaâ€™s prior written consent, grant to any Third Party any license or other right, or any lien or security interest, with respect to any of the Passage Technology in a manner that would conflict with or impair any of the rights or licenses granted to Gemma hereunder.9.5Gemma Covenants. Â Gemma hereby covenants to Passage that it shall, and shall cause its Affiliates, Sublicensees and subcontractors to (a) not directly or indirectly (including where the same is done by a Third Party on behalf of Gemma or its Affiliates, at the urging of Gemma or its Affiliates or with the assistance of Gemma or its Affiliates) institute or make any Challenge of any Licensed UPenn Patents; provided, however, that if any Licensed UPenn Patent is asserted against Gemma or its Affiliates for activities authorized under this Agreement, then Gemma or its Affiliates (or the Sublicensee or sub-Sublicensee) is entitled to all and any defenses available to it including challenging the validity or enforceability of such Patent Right; (b) comply with all Laws that apply to its activities or obligations under this Agreement (e.g., Gemma will comply with applicable United States export laws and regulations) and Gemma acknowledges and agrees the transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Gemma that Gemma will not export data or commodities to certain foreign countries without the prior approval of the agency; and (c) not grant a security interest in any Licensed UPenn Patents.9.6No Other Warranties.9.6.1EXCEPT AS EXPRESSLY SET FORTH HEREIN, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF PASSAGE, GEMMA, OR THEIR RESPECTIVE AFFILIATES; AND (B) ALL OTHER WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY DISCLAIMED BY THE PARTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. Â PASSAGE MAKES NO WARRANTY, EITHER EXPRESS OR IMPLIED, THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF 35â€‹â€‹â€‹THE LICENSED COMPOUND OR LICENSED PRODUCTS WILL BE SUCCESSFUL OR ACHIEVE ANY PARTICULAR RESULT.9.6.2Furthermore, nothing in this Agreement will be construed as:(a)A representation or warranty by Passage as to the validity or scope of any Licensed UPenn Patents; (b)A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;(c)Obligating Passage to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement; and(d)Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Passage other than the Licensed UPenn Patents as defined herein, regardless of whether such Patent Rights are dominant or subordinate to the Licensed UPenn Patents.9.6.3Gemma acknowledges and agrees that it has conducted diligence relating to the Passage Technology, and has been offered the opportunity to ask representatives of Passage questions about the Passage Technology. Â Passage represents that it has provided such available information as Licensee has requested relating to such Passage Technology and any additional available information that Passage knows to be material to the diligence conducted by Gemma.Article 10â€‹INDEMNIFICATION10.1Indemnification by Gemma.10.1.1Indemnification of Passage. Â Gemma shall defend, indemnify and hold Passage, its Affiliates and their respective directors, officers, employees, contractors and agents (the â€œPassage Indemniteesâ€) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneysâ€™ fees), including, bodily injury, risk of bodily injury, death and property damage (collectively, â€œLossesâ€) arising out of Third Party claims or suits (each, a â€œThird Party Claimâ€) related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; (b) any breach of this Agreement by Gemma; or (c) the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Gemma or its Affiliates or Sublicensees; except, in each case (a)-(c), to the extent such Losses arise out of any conditions set forth in Sections 10.2(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 10.2.36â€‹â€‹â€‹10.1.2Indemnification of Passage under the UPenn Agreement. Â Without limiting Section 10.1.1, Gemma shall defend, indemnify and hold the Passage Indemnitees harmless from and against any and all Losses related to either (or both) of the UPenn Letter Agreements or a breach of the UPenn Agreement by Passage, in each case, caused by any acts or omissions of a Gemma Indemnitee; except to the extent such Losses arise out of any conditions set forth in Sections 10.2(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 10.2.10.1.3Indemnification of Penn. Â Gemma shall defend, indemnify and hold Penn and its respective trustees, officers, faculty, students, employees, contractors and agents (the â€œPenn Indemniteesâ€) harmless from and against any and all Losses arising out of a Third Party Claim related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; (b) any breach of this Agreement by Gemma; (c) the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Gemma or its Affiliates or Sublicensees; or (d) any enforcement action or suit brought by Gemma against a Third Party for infringement of any UPenn Patent; provided that Gemmaâ€™s obligations pursuant to this Section 10.1.3 shall not apply to the extent such claims or suits result from the gross negligence or willful misconduct of any of Penn Indemnitees as determined by a court of law. 10.2Indemnification by Passage. Â Passage shall defend, indemnify and hold Gemma, its Affiliates and their respective directors, officers, employees, contractors and agents (the â€œGemma Indemniteesâ€) harmless from and against any and all Losses arising out of any Third Party Claim related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Passage, its Affiliates and its or their respective directors, officers, employees and agents, in connection with Passageâ€™s performance of its obligations or exercise of its rights under this Agreement; or (b) any breach of this Agreement by Passage; except, in each case (a)-(b), to the extent such Losses arise out of any conditions set forth in Sections 10.1(a)-(c) for which Gemma is obligated to indemnify any Passage Indemnitee under Section 10.1.10.3Procedure. 10.3.1Notice. Â The Party seeking indemnification under Section 10.1 or Section 10.2 (the â€œIndemnified Partyâ€) shall inform the other Party (the â€œIndemnifying Partyâ€) of the Third Party Claim giving rise to the obligation to indemnify pursuant to such Section within [*] after receiving written notice of such Third Party Claim, it being understood and agreed, however, that the failure or delay by an Indemnified Party to timely give such notice shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party is actually and materially prejudiced as a result of such failure or delay to give notice.10.3.2Procedure. Â The Indemnifying Party shall assume and conduct the defense of the Third Party Claim using counsel of its choice; provided, however, that the Indemnified Party may participate in and monitor such defense with counsel of its choice at its own expense, subject to the Indemnifying Partyâ€™s right to control such defense. Â With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense: (a) the Indemnified Party shall provide 37â€‹â€‹â€‹the Indemnifying Party with reasonable assistance, at the Indemnifying Partyâ€™s expense, in connection with such defense, (b) the Indemnifying Party shall not settle any Third Party Claim without the prior written consent of the Indemnified Party if the settlement would: (i) result in or impose any obligation (including any payment obligation) on the Indemnified Party, or (ii) result in any admission of wrong-doing or fault by the Indemnified Party, and (c) so long as the Indemnifying Party is actively defending the Third Party Claim in good faith, the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party. Â If the Parties cannot agree as to the application of Section 10.1 or Section 10.2 to any Third Party Claim, pending resolution of the dispute pursuant to Section 12.6, the Parties may conduct separate defenses of such Third Party Claim(s), with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or Section 10.2, as applicable, upon resolution of the underlying claim. Â If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, (A) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate, and (B) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided under Section 10.1 or Section 10.2. Â Notwithstanding anything to the contrary in this Section 10.3.2, in the event that Passage or Penn believes in good faith that a bona fide conflict exists between Gemma and Passage or Penn or any other Passage Indemnitee or Penn Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Passage or Penn or any other Passage Indemnitee or Penn Indemnitee shall have the right to defend against any such claim or suit itself, including by selecting its own counsel, with any reasonable attorneyâ€™s fees and litigation expenses being paid for by Gemma. Â Gemma will pay such fees and expenses either directly or will reimburse such Person within [*] after Gemmaâ€™s receipt of an invoice for such fees and expenses.10.4Insurance. Â Within [*] of the Effective Date, Gemma shall (and shall cause its Affiliates to) obtain commercial general liability, product liability and other appropriate insurance in an amount consistent with industry standards in light of its obligations under this Agreement, including:10.4.1Commercial Form General Liability Insurance (contractual liability included) with limits no less than as follows:(a)Each occurrence [*]; (b)General aggregate [*]; and10.4.2Prior to the commencement of Clinical Studies: (a)Clinical trials liability insurance with limits no less than [*]; and10.4.3Prior to the First Commercial Sale: (a)Products liability insurance with limits no less than[*]. Gemma shall (and shall cause its Affiliates and Sublicensees to) maintain such insurance (including in the amounts set forth above) during the Term and for [*] thereafter. Â Passage may 38â€‹â€‹â€‹review periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section, and has the right to require Gemma to adjust the limits in Passageâ€™s reasonable discretion.10.4.4Gemma expressly understands, however, that the coverages and limits in this Section 10.4 do not in any way limit Gemmaâ€™s liability or indemnification obligations. Â Gemmaâ€™s insurance will: (a)Be issued by an insurance carrier with an [*] or better; (b)Provide for [*] advance written notice to Passage and Penn of any modification; (c)State that Passage and Penn are endorsed as an additional insured with respect to the coverages in this Section 10.4; and (d)Include a provision that the coverages will be primary and will not participate with nor will be excess over any valid and collective insurance or program of self-insurance carried or maintained by Passage or Penn.10.4.5Gemma shall furnish to Passage (and if requested by Passage, Penn) (a) a valid certificate of insurance evidencing compliance with all requirements of this Agreement, and (b) additional insured endorsements for Gemmaâ€™s applicable policies naming Passage and â€œThe Trustees of the University of Pennsylvaniaâ€ as additional insureds. Â Gemma shall furnish both documents within [*] after the Effective Date, once per year thereafter, and at any time there is a modification in or to such insurance.10.5Limitation of Liability. Â EACH PARTY AND ITS AFFILIATES SHALL NOT BE LIABLE TO THE OTHER PARTY AND ITS AFFILIATES FOR (A) ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES, OR (B) ANY LOSS OF PROFITS OR REVENUE, IN EACH CASE (A) AND (B) ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF WHETHER SUCH CLAIM IS IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. Â NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (I) A PARTYâ€™S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.1 OR SECTION 10.2, OR (II) LIABILITIES ARISING FROM A PARTYâ€™S BREACH OF ITS OBLIGATIONS UNDER SECTION 3.1 OR ARTICLEÂ 7.Article 11â€‹TERM AND TERMINATION11.1Term. Â This Agreement shall be effective commencing on the Effective Date and shall expire in its entirety upon the expiration of the last to expire Royalty Term with respect to all Licensed Products and all countries (the â€œTermâ€), unless terminated earlier in accordance with this Article 11 or by mutual written agreement of the Parties. Â Following the expiration of the Royalty Term for a Licensed Product in a particular country, the License shall become non-exclusive, fully paid-up and royalty-free (subject to any payments owed under the UPenn 39â€‹â€‹â€‹Agreement in and for such country), perpetual, and irrevocable for such Licensed Product in and for such country. Â Upon the expiration of the Term, the License shall become non-exclusive, fully paid-up and royalty-free (subject to any payments owed under the UPenn Agreement), perpetual, and irrevocable in its entirety.11.2Termination for Diligence Event Failure. In the event Gemma fails to achieve any Diligence Event by the corresponding Achievement Date (as the same may be extended under this Agreement in accordance with Section 6.7) and does not cure such breach within [*] after Gemmaâ€™s receipt of

written notice (or a longer period of up to [*] if the Parties mutually agree that such longer period is necessary and acceptable) to the reasonable satisfaction of Passage or Penn, as applicable, Passage shall have the right and option to terminate this Agreement, upon written notice, with immediate effect. 11.3Termination for Convenience; Termination for Cause.(a) Gemma may, at its convenience, terminate this Agreement in its entirety or terminate a Licensed Product for the Indication in the Field of Use, upon providing at least [*] prior written notice to Passage of such intention to terminate, provided that upon termination of a Licensed Product, except as set forth in Section 11.7.3, Gemma shall cease using the License for making, using, or selling the affected Licensed Product for the Indication in the Field of Use; provided further, that Gemma may not terminate this Agreement in its entirety or terminate a Licensed Product for the Indication in the Field of Use, in either case for convenience prior to the first anniversary of the Effective Date and full payment of the amounts due to Passage under Section 5.1.(b) Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and does not cure such breach within [*] (or within [*] with respect to a breach of any payment obligation) following receipt of written notice of such breach from the non-breaching Party; provided however, that if the breach is capable of being cured, but cure of such breach cannot reasonably be effected within such [*] period, then the cure period shall be extended an additional [*] (for a total of [*] following receipt of written notice of such breach from the non-breaching Party). Â Additionally, Passage shall have the right to terminate this Agreement in its entirety (i) upon [*] written notice if Gemma fails to comply with any Laws that apply to its activities or obligations under this Agreement, which failure(s) can be remedied, and Gemma fails to remedy such lack of compliance within such [*] period, and (ii) upon written notice, with immediate effect, if Gemma grants a security interest in any Licensed UPenn Patents.11.4Termination for Bankruptcy. Â 11.4.1Right to Terminate. Â Each Party shall have the right to terminate this Agreement effective immediately upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [*] of its filing, 40â€‹â€‹â€‹or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.11.4.2Rights in Bankruptcy. Â All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of SectionÂ 365(n) of Title 11 of the United States Code (â€œUS Bankruptcy Codeâ€) or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to â€œintellectual propertyâ€ as defined under SectionÂ 101 of the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. Â In the event that a case under the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws is commenced by or against a Party, the other Party shall have all of the rights and elections set forth in Section 365(n) or comparable provision of applicable bankruptcy or insolvency laws to the maximum extent permitted thereby. Â The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the US Bankruptcy Code or any comparable provision of applicable bankruptcy or insolvency laws, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in such other Partyâ€™s possession, shall be promptly delivered to such other Party (i) upon any such commencement of a bankruptcy proceeding upon such other Partyâ€™s written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i), following the rejection of this Agreement by such Party upon written request therefor by such other Party. Â The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws: (a) the right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development, Manufacture or Commercialization of the Licensed Products; (b) the right to contract directly with any Third Party described in (a) to complete the contracted work; and (c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement. Â 11.5Termination for Patent Challenge. Â In the event that Gemma or any of its Affiliates or Sublicensees directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any Licensed UPenn Patent as being invalid, unenforceable or otherwise not patentable, this Agreement shall immediately and automatically terminate in its entirety upon the initiation of such challenge, with or without any further action by Passage; provided, however, that this Agreement shall not so automatically terminate if Gemma (or its Affiliate) or such Sublicensee challenged such Licensed UPenn Patent in defense of claims asserted by or on behalf of Passage (or its Affiliate) against Gemma (or its Affiliate) or such Sublicensee, for activities authorized under this Agreement pursuant to Section 9.5(a). Â 11.6Full Force and Effect During Notice Period. Â This Agreement shall remain in full force and effect during the period commencing on the date of notice of termination of this Agreement and ending on the effective date of termination of this Agreement, including that Gemma shall owe royalties on Net Sales of Licensed Products made during such period, and shall be obligated to make any Development Milestone Payment or Sales Milestone Payment achieved 41â€‹â€‹â€‹during such period, even if the due date of such payment comes after the effective date of termination.11.7Effect of Termination. Â Without limiting any other legal or equitable remedies that either Party may have under this Agreement, in the event of termination of this Agreement in its entirety for any reason, the terms of this Section 11.7 will apply as of the effective date of such termination. Â 11.7.1Licenses. Â All rights and licenses granted by either Party to the other Party pursuant to this Agreement shall terminate, and, subject to Section 11.7.2, all sublicenses granted hereunder by Gemma or its Affiliates shall also terminate. Â 11.7.2Sublicense Survival. Â Upon termination of this Agreement for any reason (other than any such termination that results in the termination of the UPenn Agreement with respect to the Indication), upon the request of any Third Party Sublicensee, Passage will enter into a direct license with such Sublicensee on the same terms as this Agreement, taking into account any differences in license scope, territory and duration of the sublicense grant and, subject to the proviso in this sentence, Passage will, and does hereby grant to each such Sublicensee, a direct license during the period from the termination of this Agreement until Passage and each such Sublicensee have entered into such direct license (each a â€œNew License Agreementâ€); provided that, at the time of such termination, (a) such Sublicensee is not in breach of its sublicense agreement with Gemma or its Affiliate, and (b) the UPenn Agreement remains in full effect with respect to the Indication. Â Under any such New License Agreement between Passage and such former Sublicensee, such former Sublicensee will be required to pay to Passage the same amounts in consideration for such direct license as Passage would have received from Gemma pursuant to this Agreement on account of such former Sublicenseeâ€™s Development or Commercialization of Licensed Products had this Agreement not been terminated. Â Under such New License Agreement, Passage will not be bound by any grant of rights broader than, and will not be required to perform any obligations other than those rights and obligations contained in this Agreement, and all applicable rights of Passage set forth in this Agreement will be included in such New License Agreement. Â Notwithstanding the foregoing, Passage will not be obligated to enter into a New License Agreement with a Third Party Sublicensee of Gemma unless such Sublicensee notifies Passage within [*] after the termination of this Agreement that it wishes to enter into a New License Agreement.11.7.3Winddown; Sell-Off. Â Gemma shall be responsible for the prompt wind-down of Gemmaâ€™s, its Affiliatesâ€™ and their respective Sublicenseesâ€™ Development, Manufacturing and Commercialization of the Licensed Products in the Territory in compliance with Law. Â Notwithstanding the foregoing, other than in the event of termination of this Agreement by Passage pursuant to Section 11.2, Section 11.3(b), or Section 11.4, and so long as the UPenn Agreement is still in effect with respect to the Licensed Products, during the [*] period following the effective date of termination, Gemma and its Affiliates and Sublicensees shall have the right to sell or otherwise dispose of all Licensed Products for the Indication then in its or their respective inventory and any in-progress inventory; provided that Gemma shall continue to make payments to Passage on Net Sales of such Licensed Products in accordance with SectionÂ 5.4, and the rights and licenses granted to Gemma hereunder shall survive to the extent necessary for Gemma (and its Affiliates and Sublicensees) to conduct such sell-off. Â Except in connection with activities 42â€‹â€‹â€‹pursuant to the foregoing, Gemma, its Affiliates and, subject to Section 11.7.2, Sublicensees shall cease all exploitation of the Licensed Products. Â 11.8Program Reversion. Â Passage shall have, and Gemma hereby grants to Passage, effective upon termination of this Agreement for any reason other than in the event of termination of this Agreement by Gemma pursuant to [*], a worldwide, fully-paid, royalty-free, perpetual, irrevocable, sublicensable (through multiple tiers) exclusive license under any Gemma Collaboration Know-How and Gemma Collaboration Patents solely to Develop, Manufacture, and Commercialize the Licensed Products in the Indication in the Field of Use in the Territory. Â In addition, upon Passageâ€™s request in writing within [*] after the effective date of termination, subject to Section 11.7.2, Gemma shall (and shall cause its Affiliates and Sublicensees to) (i) transfer and assign to Passage or its designee all Regulatory Submissions and Regulatory Approvals Controlled by Gemma, its Affiliates or Sublicensees for the Licensed Products in the Indication in the Field of Use, and (ii) transfer, or at Passageâ€™s election, wind-down the conduct of any ongoing Clinical Studies for a Licensed Product in the Indication in the Field of Use then being conducted by Gemma, its Affiliates or Sublicensees to Passage or its designee, or (iii) subject to Section 11.7.3, transfer to Passage all inventory of Licensed Products in the Indication then Controlled by Gemma, its Affiliates or Sublicensees at the actual cost of such supply, plus any reasonable costs associated with such transfer; provided that other than in the event of termination of this Agreement pursuant to Section 11.3(b) by Gemma, all such transfers (or wind-downs) shall be at Gemmaâ€™s sole cost and expense.11.9Confidential Information. Â Upon the expiration or termination of this Agreement in its entirety, at the disclosing Partyâ€™s election, the receiving Party shall return or destroy all tangible materials to the extent comprising, bearing or containing any Confidential Information of the disclosing Party that are in the receiving Partyâ€™s or its Affiliatesâ€™ respective possession or control and provide written certification of such destruction (if applicable) to the disclosing Party; provided that the receiving Party may retain one (1) copy of such Confidential Information for its archives solely to monitor compliance with its obligations herein or may retain such Confidential Information for which it has any continuing rights; and provided further that the receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures.11.10Termination Not Sole Remedy. Â Termination is neither Partyâ€™s sole remedy under this Agreement and, whether or not termination is effected by a Party and notwithstanding anything contained in this Agreement to the contrary, all other remedies in law or equity shall remain available to both Parties except as agreed to otherwise herein.11.11Survival. Â Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Â In addition, the following provisions of this Agreement shall survive expiration or termination of this Agreement: Article 1, Article 7, Article 8, Article 10, Article 11, Article 12, and Sections 2.6, 5.11, and 9.6.Article 12â€‹MISCELLANEOUS43â€‹â€‹12.1Assignment. Â 12.1.1Generally. Â This Agreement may not be assigned or transferred by either Party in whole or in part without the prior written consent of the other Party. Â Notwithstanding the foregoing, either Party shall have the right, without the prior written consent of the other Party, to assign or transfer this Agreement or its rights and obligations hereunder to (i) its Affiliate, or (ii) its successor in interest in connection with a Change of Control. Â A Party shall notify the other Party in writing of any assignment of this Agreement by such Party within [*] thereof. Â The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the applicable Party. Â Any attempted assignment not in accordance with this Section 12.1 shall be void. Â Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.12.1.2Effect of Change of Control.(a)Whether or not this Agreement is assigned by Passage pursuant to Section 12.1.1, the Parties agree that all Patent Rights, Know-How, Regulatory Materials, Materials or other intellectual property rights of any Acquiror of Passage will be deemed not to be â€œControlledâ€ by Passage for purposes of this Agreement and will be automatically excluded from the rights licensed to Gemma under this Agreement. (b)Notwithstanding anything in Section 5.1 to the contrary, any unpaid portion of the amounts due to Passage under Section 5.1 shall become immediately due and payable to Passage upon a Change of Control.12.2Use of Affiliates. Â Either Party shall have the right to exercise its rights and perform its obligations under this Agreement through any of its Affiliates. Â In each case where a Partyâ€™s Affiliate has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement, (a) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement, and (b) any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions. 12.3No Discrimination. Â Neither Party will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.12.4Severability. Â Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.12.5Governing Law; English Language. Â This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, without reference to any rules of conflict of laws that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Â The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable. Â 44â€‹â€‹â€‹This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.12.6Dispute Resolution.12.6.1Disputes. Â Any dispute, controversy or claim arising from or related to this Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination hereof (a â€œDisputeâ€) that is not an Excluded Claim (as defined below) shall be finally resolved in accordance with Section 12.6.2. Â Notwithstanding the foregoing, any decisions that are subject to mutual agreement of the Parties will not be subject to the provisions of this Section 12.6 so long as such decisions are made in accordance with this Agreement.12.6.2Early Resolution; Arbitration. Â (a)Early Resolution. Â Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Â Any final decision mutually agreed to by the Executive Officers shall be set forth in writing and shall be conclusive and binding on the Parties. Â If the Executive Officers are not able to agree on the resolution of any such Dispute within [*] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then the Parties shall submit such Dispute to be finally resolved by arbitration in accordance with Section 12.6.2(b). Â To the extent any Dispute relates to an action or decision required to be taken or made under the UPenn Agreement within a certain time period, the Parties shall use their best efforts to resolve such Dispute within such time period required for such action or decision. To the extent any such Dispute has not been resolved with such time period, and notwithstanding anything herein to the contrary, Passage shall have final decision making authority with respect to, and nothing herein shall prevent Passage from taking or making, any such action or decision required to be taken or made under the UPenn Agreement within such time period.(b)Arbitration. Â Any arbitration will be administered by the American Arbitration Association (â€œAAAâ€) in accordance with the AAAâ€™s Commercial Arbitration Rules in effect at the time of submission, as modified by this Section 12.6.2(b). Â The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the biopharmaceutical industry, each of whom will be impartial and independent. Â Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [*] following appointment of the second arbitrator, by the AAA. Â Such arbitration will take place in Philadelphia, Pennsylvania and will be conducted in English. Â The arbitration award will be a final and binding determination of the Dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 10.5. Â Subject to any award by the arbitration panel, each Party shall be responsible for its fees, costs, and expenses for conducting the arbitration; provided that the Parties will share payment for the third arbitrator. Â 12.6.3Confidentiality. Â Except to the extent necessary to comply with Law, legal process or a court order, or to enforce a final settlement agreement or secure enforcement of any arbitration award, the Parties agree that the existence, terms and content of any arbitration pursuant 45â€‹â€‹â€‹to Section 12.6.2(b), all information and documents disclosed in any such arbitration or evidencing any such arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any such arbitration, shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.12.6.4Excluded Claims. Â As used in this Section 12.6, the term â€œExcluded Claimâ€ means a dispute, controversy or claim that concerns (a) the validity or infringement of a Patent Right, trademark, copyright, or trade secret, or (b) any antitrust-, anti-monopoly- or competition-related Law. Â Any action concerning Excluded Claims may be brought in any court having jurisdiction.Â 12.6.5Equitable Relief. Â Nothing in this Section 12.6 shall preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief, either prior to or during any arbitration, to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.12.7Waivers and Amendments. Â The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other

right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Â Any waivers under this Agreement must be in writing to be effective. Â No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.12.8Relationship of the Parties. Â The Parties have the relationship of independent contractors to each other under this Agreement, and nothing contained herein is intended or is to be construed so as to constitute one Party as a partner, agent, or joint venturer of the other Party. Â In addition, nothing in this Agreement shall be construed to give a Party the power or authority to act for, bind or commit the other Party or its Affiliates to or under any contract, agreement, or undertaking with any Third Party.12.9Notices. Â All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file) and sent as an attachment to an e-mail message, or (b) the earlier of when received by the addressee or [*] after the date it was sent, if sent by registered mail or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses or e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):If to Passage: Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: Chief Executive Officerâ€‹46â€‹â€‹â€‹With a copy to (which shall not constitute notice):Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: General Counselâ€‹If to Gemma:Gemma Biotherapeutics, Inc.1831 Delancey PlacePhiladelphia, PA 19103ATTN: Chief Executive Officerâ€‹With a copy to (which shall not constitute notice): McDermott Will & Emery LLP200 Clarendon Street, Floor 58Boston, MA 02116ATTN: Brian Bunnâ€‹â€‹12.10No Third Party Beneficiary Rights. Â This Agreement is not intended to and shall 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 this Agreement or any provision contained herein or contemplated hereby. Â Notwithstanding the foregoing, each of Passage and Gemma agree and acknowledge that Penn is an intended third party beneficiary, and is entitled to rely on, the representations, warranties and covenants of Gemma, and remedies, set forth herein as if an original party to this Agreement.12.11Further Assurances. Â Passage and Gemma hereby agree without the necessity of any further consideration to execute, acknowledge, and deliver any and all administrative documents and take any ministerial action as may be reasonably necessary to carry out the intent and purposes of this Agreement.12.12Entire Agreement. Â This Agreement, the UPenn Agreement, and the Transition Services Agreement, including all Exhibits and Schedules hereto and thereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter, including the CDA.12.13Counterparts. Â This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. Â All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Â Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an â€œElectronic Deliveryâ€) shall be treated in all manners and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Â Neither Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature 47â€‹â€‹â€‹or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity. 12.14Expenses. Â Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and signing of this Agreement.12.15Construction. Â The Parties acknowledge and agree that (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, and (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement. 12.16Interpretation. Â The captions and headings in this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Â Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits of or to this Agreement and references to this Agreement include all Exhibits and Schedules hereto. Â If any conflict exists between the main body of this Agreement and any Exhibit or Schedule hereto, the main body of this Agreement shall prevail. Â Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words â€œincludeâ€ or â€œincludingâ€ shall be construed as incorporating, also, â€œbut not limited toâ€ or â€œwithout limitation;â€ (b) the word â€œdayâ€ or â€œyearâ€ means a calendar day or year unless otherwise specified; (c) the words â€œhereof,â€ â€œherein,â€ â€œherebyâ€ and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (d) the words â€œshallâ€ and â€œwillâ€ have interchangeable meanings for purposes of this Agreement; (e) the word â€œorâ€ shall have the inclusive meaning commonly associated with â€œand/orâ€; (f) words of any gender include the other genders; (g) words using the singular or plural number also include the plural or singular number, respectively; and (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.12.17Cumulative Remedies. Â No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, and each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.12.18Export. Â This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Gemma or Passage from time to time. Â Each Party agrees that it will not export, directly or indirectly, any 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 Body approval, without first obtaining the written consent to do so from the appropriate Governmental Body.[Signature page follows]48â€‹â€‹â€‹IN WITNESS WHEREOF, the Parties intending to be legally bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.â€‹Passage Bio, Inc.Gemma Biotherapeutics, Inc.â€‹â€‹By: _/s/ Will Chou_____â€‹By: _/s/ Annalisa Jenkins_____Name: Will Chou, M.D.â€‹Name: Annalisa JenkinsTitle: Chief Executive OfficerTitle: Presidentâ€‹â€‹â€‹List of Schedules:â€‹Schedule 1.60: Licensed CompoundSchedule 1.119: UPenn Patents (existing as of the Effective Date)â€‹List of Exhibits:â€‹Exhibit A: Specified ObligationsExhibit B: Form of SDR ReportExhibit C: Form of Financial ReportExhibit D: Third Party MilestonesExhibit E: Diligence Eventsâ€‹â€‹[Signature Page to Exclusive License Agreement (GM1)]â€‹â€‹SCHEDULE 1.60LICENSED COMPOUNDâ€‹[*] â€‹â€‹â€‹â€‹â€‹SCHEDULE 1.119UPENN PATENTSâ€‹[*]â€‹â€‹â€‹â€‹EXHIBIT ASPECIFIED OBLIGATIONSâ€‹[*]â€‹â€‹â€‹â€‹â€‹â€‹EXHIBIT BFORM OF SDR REPORTâ€‹[*]â€‹â€‹â€‹â€‹EXHIBIT CFORM OF FINANCIAL REPORTâ€‹[*]â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹EXHIBIT DTHIRD PARTY MILESTONESâ€‹[*]â€‹â€‹â€‹â€‹â€‹â€‹â€‹â€‹EXHIBIT EDILIGENCE EVENTSâ€‹[*]â€‹â€‹â€‹â€‹Exhibit 10.2â€‹Execution VersionConfidentialâ€‹â€‹â€‹CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT PASSAGE BIO, INC. TREATS AS PRIVATE OR CONFIDENTIAL.â€‹EXCLUSIVE LICENSE AGREEMENTby and betweenPassage Bio, Inc.andGemma Biotherapeutics, INC.July 31, 2024â€‹â€‹â€‹â€‹â€‹ConfidentialTABLE OF CONTENTSPageArticle 1 DEFINITIONS & INTERPRETATIONâ€Œ2Article 2 LICENSEâ€Œ152.1Exclusive License to Gemmaâ€Œ152.2Retained Rightsâ€Œ152.3Right to Sublicenseâ€Œ152.4Right to Subcontractâ€Œ162.5Right of Access and Referenceâ€Œ172.6No Implied Licensesâ€Œ172.7Upstream Licenseâ€Œ172.8Third Party Licensesâ€Œ18Article 3 EXCLUSIVITYâ€Œ183.1Exclusivityâ€Œ183.2Exception for Change of Controlâ€Œ18Article 4 GOVERNANCEâ€Œ194.1Alliance Managersâ€Œ194.2Cooperation with UPenn Agreement Committeesâ€Œ19Article 5 PAYMENTSâ€Œ195.1Product Supply; Upfront Feeâ€Œ195.2Development and Regulatory Milestonesâ€Œ195.3Sales Milestonesâ€Œ205.4Royalty Paymentsâ€Œ205.5Payment Termsâ€Œ225.6Payment Currency; Exchange Rate; Offsetâ€Œ225.7Late Paymentsâ€Œ235.8Payments to Third Partiesâ€Œ235.9Accountingâ€Œ235.10Records and Audit Rightsâ€Œ235.11Taxesâ€Œ245.12Blocked Currencyâ€Œ24Article 6 DEVELOPMENT AND COMMERCIALIZATIONâ€Œ246.1Development Planâ€Œ246.2Clinical Developmentâ€Œ246.3Commercializationâ€Œ256.4Manufacturingâ€Œ256.5Regulatoryâ€Œ256.6General Diligenceâ€Œ256.7Diligence Eventsâ€Œ25iâ€‹â€‹6.8Progress Reportsâ€Œ26Article 7 CONFIDENTIALITYâ€Œ267.1Confidential Informationâ€Œ267.2Duty of Confidence; Exceptionsâ€Œ277.3Authorized Disclosuresâ€Œ277.4Prior Confidentiality Agreementsâ€Œ287.5Public Disclosures; Securities Filingsâ€Œ287.6Use of Namesâ€Œ29Article 8 INTELLECTUAL PROPERTYâ€Œ298.1Ownershipâ€Œ298.2Patent Prosecution and Maintenanceâ€Œ298.3Cooperation for Patent Extensionsâ€Œ308.4Patent Listingsâ€Œ308.5Common Interest Disclosuresâ€Œ308.6Patent Enforcementâ€Œ308.7Infringement of Third Party Rightsâ€Œ318.8Patent Markingâ€Œ328.9Trademarksâ€Œ32Article 9 REPRESENTATIONS, WARRANTIES, AND COVENANTSâ€Œ329.1Representations and Warranties of Each Partyâ€Œ329.2Representations and Warranties of Passageâ€Œ339.3Mutual Covenantsâ€Œ339.4Passage Covenantsâ€Œ349.5Gemma Covenantsâ€Œ349.6No Other Warrantiesâ€Œ34Article 10 INDEMNIFICATIONâ€Œ3510.1Indemnification by Gemmaâ€Œ3510.2Indemnification by Passageâ€Œ3610.3Procedureâ€Œ3610.4Insuranceâ€Œ3710.5Limitation of Liabilityâ€Œ38Article 11 TERM AND TERMINATIONâ€Œ3811.1Termâ€Œ3811.2Termination for Diligence Event Failureâ€Œ3911.3Termination for Convenience; Termination for Causeâ€Œ3911.4Termination for Bankruptcyâ€Œ3911.5Termination for Patent Challengeâ€Œ4011.6Full Force and Effect During Notice Periodâ€Œ4011.7Effect of Terminationâ€Œ4111.8Program Reversionâ€Œ4211.9Confidential Informationâ€Œ4211.10Termination Not Sole Remedyâ€Œ42iiâ€‹â€‹11.11Survivalâ€Œ42Article 12 MISCELLANEOUSâ€Œ4212.1Assignmentâ€Œ4312.2Use of Affiliatesâ€Œ4312.3No Discriminationâ€Œ4312.4Severabilityâ€Œ4312.5Governing Law; English Languageâ€Œ4312.6Dispute Resolutionâ€Œ4412.7Waivers and Amendmentsâ€Œ4512.8Relationship of the Partiesâ€Œ4512.9Noticesâ€Œ4512.10No Third Party Beneficiary Rightsâ€Œ4612.11Further Assurancesâ€Œ4612.12Entire Agreementâ€Œ4612.13Counterpartsâ€Œ4612.14Expensesâ€Œ4712.15Constructionâ€Œ4712.16Interpretationâ€Œ4712.17Cumulative Remediesâ€Œ4712.18Exportâ€Œ47â€‹â€‹â€‹â€‹â€‹â€‹iiiConfidentialEXCLUSIVE LICENSE AGREEMENTThis Exclusive License Agreement (this â€œAgreementâ€) is entered into as of July 31, 2024 (the â€œEffective Dateâ€), by and between Passage Bio, Inc., a corporation organized under the laws of Delaware (â€œPassageâ€), with offices at 2005 Market St., 39th Floor, Philadelphia, PA 19103, and Gemma Biotherapeutics, Inc., a Delaware corporation (â€œGemmaâ€), with offices at 1831 Delancey Place, Philadelphia, PA 19103. Â Passage and Gemma may be referred to in this Agreement individually as a â€œPartyâ€ or collectively as the â€œParties.â€BACKGROUNDWHEREAS, Passage is a biopharmaceutical company with expertise in the development, manufacture and commercialization of human therapeutic products for the treatment of genetic disorders;WHEREAS, concurrently with the execution of this Agreement, Passage and The Trustees of the University of Pennsylvania (â€œPennâ€) are also entering into that certain Second Amended and Restated Research, Collaboration & License Agreement, effective as of September 18, 2018, and amended and restated as of the Effective Date (as amended and restated, the â€œUPenn Agreementâ€);WHEREAS, concurrently with the execution of this Agreement, Passage and Gemma are also entering into (a) that certain Exclusive License Agreement, pursuant to which Passage will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for Metachromatic leukodystrophy (the â€œMLD License Agreementâ€), and (b) that certain Exclusive License Agreement, pursuant to which Passage will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for GLB1 Deficiency, for GM1 gangliosidosis-1 and MPS IV;WHEREAS, the programs contemplated by this Agreement are of mutual interest to Passage and Gemma, and may benefit Passage and Gemma through the creation or discovery of new inventions and the development and commercialization of Licensed Products (as defined herein) for the Indication (as defined herein);WHEREAS, Gemma wishes to obtain from Passage worldwide, exclusive and non-exclusive licenses to rights granted to Passage under the UPenn Agreement and certain other intellectual property rights owned or controlled by Passage, to develop, manufacture and commercialize Licensed Products for the Indication, and Passage is willing to grant such licenses to Gemma in accordance with the terms and conditions set forth herein; andWHEREAS, concurrently with the execution of this Agreement, Passage and Gemma are also entering into the Transition Services Agreement (as defined herein);NOW THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:1â€‹â€‹Article 1â€‹DEFINITIONS & INTERPRETATIONWhenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, whether used in the singular or plural, shall have the meanings specified.1.1â€œAAAâ€ has the meaning set forth in Section 12.6.2(b).1.2â€œAcquirorâ€ means a Third Party that acquires a Party through a Change of Control, together with any Affiliates of such Third Party existing immediately prior to the consummation of the Acquisition. Â For clarity, an â€œAcquirorâ€ of a Party shall exclude the Party and all of its Affiliates existing immediately prior to the consummation of the Acquisition.1.3â€œAffiliateâ€ means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. Â For the purposes of this Section 1.3, the word â€œcontrolâ€ (including, with correlative meaning, the terms â€œcontrolled byâ€ or â€œunder common control withâ€) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such Person, by contract or otherwise.1.4â€œAlliance Managerâ€ has the meaning set forth in Section 4.1.1.5â€œArising Know-Howâ€ means any and all Know-How, whether or not patentable, generated, created, developed, conceived, reduced to practice, or otherwise made during the Term by or on behalf of Gemma, its Affiliates or Sublicensees in the performance of activities under this Agreement.1.6â€œAuditing Partyâ€ has the meaning set forth in Section 5.10.2.1.7â€œBiosimilar Actionâ€ has the meaning set forth in Section 8.6.4.1.8â€œBLAâ€ means (a) a biologics license application as that term is used and defined in the PHS Act and the regulations promulgated thereunder, (b) a marketing authorization application in the European Union, or (c) any equivalent or comparable application, registration or certification in any other country or region.1.9â€œBusiness Dayâ€ means a day other than a Saturday, Sunday, or other day on which banking institutions in Philadelphia, PA, USA are authorized or required by Law to remain closed.1.10â€œCalendar Quarterâ€ mean the respective periods of three (3) consecutive calendar months ending on MarchÂ 31, JuneÂ 30, SeptemberÂ 30, and DecemberÂ 31 of each Calendar Year.1.11â€œCalendar Yearâ€ means each successive period of twelve (12) months commencing on JanuaryÂ 1 and ending on DecemberÂ 31.1.12â€œCDAâ€ has the meaning set forth in Section 7.4.2â€‹â€‹1.13â€œcGCPâ€ means the applicable then-current standards for clinical activities for pharmaceuticals or biologicals, as set forth in the FD&C Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good clinical practice as are required by any Regulatory Authority in such country.1.14â€œcGLPâ€ means the current good laboratory practice regulations promulgated by the FDA, published at 21 US C.F.R. Â§Â 58, and equivalent non-United States regulations and standards in or for the Territory, as applicable, as such current laboratory practices, regulations and standards may be amended from time to time.1.15â€œcGMPâ€ means those current practices, as amended from time to time, related to the manufacture of pharmaceutical or biological products and any precursors thereto promulgated in guidelines and regulations of standard compilations, including the cGMP Rules of the World Health Organization, the United States Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (established by the United States Department of Health and Human Services), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical or biological products, and equivalent guidelines, regulations and standards in or for the Territory, as such guidelines, regulations and standards may be amended from time to time.1.16â€œChallengeâ€ means, with respect to a Patent Right, that Gemma or a Sublicensee (including sub-Sublicensees) will be deemed to have made a â€œChallengeâ€ of such Patent Rights if Gemma or such Sublicensee (including sub-Sublicensees), respectively: (a) institutes or voluntarily joins as a party to, or causes its counsel to institute on Gemmaâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, any interference, opposition, re-examination, post-grant review or similar proceeding with respect to any such Patent Right with the US Patent and Trademark Office or any foreign patent office; or (b) makes any filing or institutes or voluntarily joins as a party to any legal proceeding, or causes its counsel to make any filing or institute or voluntarily join as a party to any legal proceeding on Gemmaâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, with a court or other Governmental Body (including, without limitation, the US Patent and Trademark Office or any foreign patent office) having authority to determine the validity, enforceability or scope of such Patent Right, in which one or more claims or allegations challenges the validity or enforceability of any such Patent Right.1.17â€œChange of Controlâ€ with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:(a)any Third Party â€œpersonâ€ or â€œgroupâ€ (as such terms are defined below) (i) is or becomes, through one or a series of transactions, the â€œbeneficial ownerâ€ (as defined below), directly or indirectly, of the then-outstanding shares of common stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total then-outstanding common stock (or foreign equivalent thereof) (the â€œOutstanding Common Stockâ€), (ii) is or becomes, through one or a series of transactions, the â€œbeneficial ownerâ€, directly or indirectly, of shares of securities, capital stock or other interests (including partnership interests) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) then-outstanding and normally entitled (without regard to the 3â€‹â€‹occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (â€œOutstanding Voting Stockâ€) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total

voting power of all Outstanding Voting Stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party), or (iii) has the power, directly or indirectly, to elect a majority of the members of the Partyâ€™s (or any direct or indirect parent entities or ultimate parent entities of such Party) board of directors (or similar governing body); or(b)such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) enters into a merger, consolidation or similar transaction with a Person (whether or not such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) is the surviving entity) (a â€œBusiness Combinationâ€), in each case, unless, following such Business Combination, (i) the individuals and entities who were the beneficial owners, respectively, of the Outstanding Common Stock and Outstanding Voting Stock of such Party (and the ultimate parent entity thereof) immediately prior to such Business Combination beneficially own, directly or indirectly, fifty percent (50%) or more of, respectively, (1) the then-outstanding shares of common stock (or foreign equivalent thereof) and (2) the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of directors, of the corporation or other entity resulting from such Business Combination (and the ultimate parent entity thereof), and (ii) fifty percent (50%) or more of the members of the board of directors (or similar governing body) of the corporation or other entity resulting from such Business Combination (and ultimate parent entity thereof, as applicable) were members of the board of directors (or similar governing body) of such Party (or ultimate parent entity of such Party, as applicable) at the time of the execution of the initial agreement, or became members of the board of directors of such corporation or other entity by virtue of the action of the board of directors (or similar governing body) of such Party (or ultimate parent entity), providing for such Business Combination; or(c)such Party (and its Affiliates) sells, exchanges, or otherwise transfers to any Third Party, directly or indirectly (including through the transfer of shares or other ownership interests in Affiliates), in one or a series of transactions, the properties and assets representing all or substantially all of such Partyâ€™s total assets (together with all or substantially all of the properties and assets of its Affiliates).For the purpose of this definition of Change of Control, (x) â€œpersonâ€ and â€œgroupâ€ have the meanings given such terms under Sections 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term â€œgroupâ€ includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act; (y) a â€œbeneficial ownerâ€ shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms â€œbeneficially ownedâ€ and â€œbeneficially ownâ€ shall have meanings correlative to that of â€œbeneficial owner.â€1.18â€œClinical Studyâ€ means a Phase 1 Study, Phase 1/2 Study, Phase 2 Study, or Phase 3 Study, or such other study in humans that is conducted in accordance with cGCP and is designed to generate data in support or maintenance of an application for Regulatory Approval.1.19â€œCombination Productâ€ means a Licensed Product that is delivered with [*] active 4â€‹â€‹ingredients or other items or services incident to the administration of any such Licensed Product (with or without [*] such other active ingredients), [*], in each such case when any of the foregoing are co-formulated, co-packaged or sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).1.20â€œCommercializeâ€ means any and all activities directed to the offering for sale and sale of a pharmaceutical or biological product, including activities directed to marketing, promoting, advertising, detailing, storing, distributing, importing, exporting, selling, and offering to sell (including receiving, accepting, and filling orders), booking and recording sales, interacting with Regulatory Authorities regarding any of the foregoing and seeking Pricing and Reimbursement Approvals. Â â€œCommercializationâ€ and â€œCommercializingâ€ have a corresponding meaning.1.21â€œCommercially Reasonable Effortsâ€ means the efforts and resources that a similarly situated biotechnology company would use for its own internally discovered technology of similar commercial potential at a similar stage of development, taking into account the likely timing of the technologyâ€™s entry into the market and any patent and other proprietary position, safety and efficacy, product profile, and the then-current competitive and regulatory environments for the product. Â Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the performing Party (a) promptly assign responsibility for such obligation to specific employee(s) who are accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.1.22â€œCompeting Productâ€ means any product other than a Licensed Product for use in the Indication in the Field of Use.1.23â€œCompetitive Infringementâ€ has the meaning set forth in Section 8.6.1.1.24â€œCompulsory Licenseâ€ means a compulsory license under the Licensed UPenn Patents obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in any country.1.25â€œConfidential Informationâ€ has the meaning set forth in Section 7.1.1.26â€œControlâ€ means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without (i) violating the terms of any other agreement or other arrangement with any Third Party from whom the Party or its Affiliate acquired such intellectual property rights, (ii) requiring additional obligations, liabilities or financial consideration to such Third Party in connection with the grant of such license or sublicense (other than consideration for which the Party or its Affiliate agrees to bear the entire cost), or (iii) violating the terms of, or requiring additional obligations, liabilities or financial consideration to a Third Party under, [*]. Â â€œControlledâ€ has a corresponding meaning.5â€‹â€‹1.27â€œCoverâ€ means (a) with respect to a claim of an issued Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof), or (b) with respect to a claim of a pending Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would, if such claim were to issue in its current form, infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof). Â â€œCoveredâ€ has a corresponding meaning.1.28â€œCROâ€ means a Third Party contract resesarch organization (for clarity, excluding consultants).1.29â€œCT Enrollment Dateâ€ means the earlier of (a) the date upon which Gemma, or any of its Affiliates or Sublicensees, either directly or through a contractor, opens enrollment at a site for a Clinical Study for a Licensed Product under this Agreement, or (b) the date upon which Gemma, or any of its Affiliates or Sublicensees, either directly or through a contractor, opens enrollment at a site for a Clinical Study for a Licensed Product (as defined in the MLD License Agreement) under the MLD License Agreement.1.30â€œData Protection Lawsâ€ has the meaning set forth in Section 9.3.1.1.31â€œDevelopâ€ means any and all pre-clinical, non-clinical and clinical research and development activities for a pharmaceutical or biological product, including activities related to preclinical research and studies, Clinical Studies, toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies, supply of such product for use in the foregoing activities (including placebos and comparators), statistical analyses, the preparation and submission of INDs, MAAs and other Regulatory Materials for the purpose of obtaining, registering and maintaining Regulatory Approval of such product, as well all interactions with Regulatory Authorities with respect to the foregoing. Â â€œDevelopingâ€ and â€œDevelopmentâ€ have a corresponding meaning.1.32â€œDevelopment Milestone Eventâ€ has the meaning set forth in Section 5.2.1.33â€œDevelopment Milestone Paymentâ€ has the meaning set forth in Section 5.2.1.34â€œDisputeâ€ has the meaning set forth in Section 12.6.1.1.35â€œDivestitureâ€ means, with respect to a Competing Product, (a) [*] (i) [*], or (ii) [*], or (b) [*] with respect to such Competing Product. Â [*]. Â â€œDivestâ€ has a corresponding meaning.1.36â€œElectronic Deliveryâ€ has the meaning set forth in Section 12.13.1.37â€œEMAâ€ means the European Medicines Agency and any successor entity thereto.1.38â€œEnforcement Actionâ€ means a legal action to enforce the Licensed UPenn Patents with respect to Competitive Infringement.1.39â€œEuropean Unionâ€ or â€œEUâ€ means the European Union.6â€‹â€‹1.40â€œExclusivity Periodâ€ has the meaning set forth in Section 3.1.1.41â€œExecutive Officersâ€ means Gemmaâ€™s Chief Executive Officer, or her or his designee, and Passageâ€™s Chief Executive Officer, or her or his designee, provided that any such designee must have decision-making authority on behalf of the applicable Party.1.42â€œFD&C Actâ€ means the United States Federal Food, Drug and Cosmetic Act, as amended.1.43â€œFDAâ€ means the United States Food and Drug Administration and any successor entity thereto.1.44â€œField of Useâ€ means all prophylactic, diagnostic and therapeutic uses in humans. Â For clarity, [*].1.45â€œFirst Commercial Saleâ€ means, on a country-by-country basis, the first commercial transfer or disposition for value of a Licensed Product in such country to a Third Party by Gemma, or any of its Affiliates or Sublicensees, in each case, after Regulatory Approval for such Licensed Product has been obtained for such country.1.46â€œFPFDâ€ means, with respect to a Licensed Product and a Clinical Study, the first dosing of the first patient in such Clinical Study.1.47â€œFTEâ€ means an individual employee of Passage or its Affiliates.1.48â€œGAAPâ€ means United States generally accepted accounting principles applied on a consistent basis.1.49â€œGemma Collaboration Know-Howâ€ means any and all Arising Know-How.1.50â€œGemma Collaboration Patentsâ€ means any and all Patent Rights that claim Gemma Collaboration Know-How.1.51â€œGemma Indemniteeâ€ has the meaning set forth in Section 10.2.1.52â€œGeneric Productâ€ means, with respect to a particular Licensed Product in a particular country or regulatory jurisdiction, a generic or biosimilar pharmaceutical product, that is not produced, licensed or owned by Gemma, any of its Affiliates or Sublicensees, that: (a) is bioequivalent or biosimilar to such Licensed Product; and (b) is approved for use in such country or regulatory jurisdiction by a Regulatory Authority by referencing the prior approval, in whole or part, or safety and efficacy data submitted in support of the prior approval, of a Licensed Product. Â Generic Product includes, but is not limited to, any pharmaceutical products for which Regulatory Approval is obtained via: (i) a bioequivalence or bioavailability showing such as those covered by section 505(j) of the FD&C Act or an equivalent outside the United States; or (ii) a biosimilarity or interchangeability determination such as those covered by section 351(k) of the PHS Act or an equivalent outside the United States.1.53â€œGovernmental Bodyâ€ means any: (a) nation, principality, state, commonwealth, 7â€‹â€‹province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.1.54â€œINDâ€ means an Investigational New Drug Application as defined in the FD&C Act and the regulations promulgated thereunder, or the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, including a Clinical Trial Authorization to the European Medicines Agency, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.1.55â€œIndemnified Partyâ€ has the meaning set forth in Section 10.3.1.1.56â€œIndemnifying Partyâ€ has the meaning set forth in Section 10.3.1.1.57â€œIndicationâ€ means Krabbe disease (globoid cell leukodystrophy) through [*].1.58â€œKnow-Howâ€ means any proprietary or confidential scientific or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form, including inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know-how, trade secrets, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, physical and analytical, safety, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process and development information, results and data. Â Know-How excludes Materials and Patent Rights.1.59â€œLawâ€ or â€œLawsâ€ means all applicable laws, statutes, rules, regulations, ordinances, and other pronouncements having the binding effect of law of any Governmental Body.1.60â€œLicenseâ€ has the meaning set forth in Section 2.1.1.61â€œLicensed Compoundâ€ means PBKR03, as more fully described in Schedule 1.61.1.62â€œLicensed Know-Howâ€ means the Licensed UPenn Know-How and Passage Know-How.1.63â€œLicensed Product(s)â€ means any (a) process, service or method covered by a Valid Claim of a UPenn Patent or whose use or practice would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim of a UPenn Patent, or would infringe a Valid Claim of a UPenn Patent once issued (â€œMethodâ€); (b) 8â€‹â€‹article, composition, apparatus, substance, chemical or any other material covered by a Valid Claim of a UPenn Patent or whose manufacture, import, use, offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim of a UPenn Patent or would infringe a Valid Claim of a UPenn Patent once issued; (c) service, article, composition, apparatus, chemical, substance or any other material made, used or sold by or utilizing or practicing a Method, or (d) any product that incorporates or makes use or is made through use of UPenn Know-How or Passage Know-How, in each case (a) through (d), for the Indication. Â Notwithstanding the foregoing, the Licensed Products shall include any product containing or comprising the Licensed Compound (alone or in the form of a Combination Product) in all forms, presentations, formulations, methods of administration and dosages.1.64â€œLicensed UPenn Know-Howâ€ means all UPenn Know-How that is necessary to Develop, Manufacture or Commercialize the Licensed Products for the Indication.1.65â€œLicensed UPenn Patentsâ€ means all UPenn Patents that are necessary to Develop, Manufacture or Commercialize the Licensed Products for the Indication.1.66â€œLossesâ€ has the meaning set forth in Section 10.1.1.1.67â€œMAAâ€ means (a) a Biologics License Application (as defined in the PHS Act) or New Drug Application (as defined in the FD&C Act) filed with the FDA to gain approval to market a biological or pharmaceutical product in the US, (b) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure to gain approval to market a biological or pharmaceutical product in the EU, or (ii) a Regulatory Authority in any EU country if the centralized EMA filing procedure is not used to gain approval to market a biological or pharmaceutical product in the EU, or (c) any equivalent application or request for authorization filed in support of approval to market a biological or pharmaceutical product in any country, in each case ((a) through (c)), including any amendments and supplements thereto but excluding applications for Pricing and Reimbursement Approval.1.68â€œMajor Marketâ€ means United States, Japan, France, Germany, Spain, Italy, and the United Kingdom.1.69â€œManufactureâ€ means all activities in connection with the manufacture of a pharmaceutical or biological product, including the processing, formulating, testing (including quality control, quality assurance and lot release testing), bulk packaging, filling, finishing, packaging, labeling, inspecting, receiving, storage, release, shipping and delivery, sourcing of materials, process qualification, validation and optimization, and stability testing of such product. Â â€œManufacturingâ€ and â€œManufacturedâ€ have a corresponding meaning.1.70â€œMaterialsâ€ means any and all biological and other physical materials.1.71â€œMLD License Agreementâ€ has the meaning set forth in the recitals.1.72â€œNet Salesâ€ means the gross consideration invoiced or received by Gemma or any of its Affiliates or Sublicensees (including all sub-Sublicensees) for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less 9â€‹â€‹the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary:(a)trade discounts, including trade, cash and quantity discounts or rebates, credits, or refunds;(b)allowances or credits actually granted upon claims, returns or rejections of products;(c)charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the Sale, transportation, delivery or return of such Licensed Product;(d)customs duties, sales, excise and use taxes actually paid in connection with the transportation, distribution, use or Sale of such Licensed Product (but excluding what is commonly known as income taxes); and(e)bad debt expense and amounts actually written off by reason of uncollectible debt not to exceed [*] of the Net Sales of Licensed Product.Even if there is overlap between any of the deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation.In the case of a Combination Product, the Parties shall negotiate in good faith, at the latest [*] before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, as the case may be, based on the fair market value of such components for the purposes of determining a product-specific allocation of such Net Sales. Â Payments related to such Combination Product under this Agreement, including Royalties and milestone payments, will be calculated, due and payable based only on the portion of such Net Sales so allocated to a Licensed Productâ€™s components.In case of disagreement and failure by the Parties to agree upon an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, [*].1.73â€œNew License Agreementâ€ has the meaning set forth in Section 11.7.2.1.74â€œNon-Exclusively Licensed Penn IPâ€ has the meaning set forth in Section 2.1.1.75â€œPassage Indemniteeâ€ has the meaning set forth in Section 10.1.1.1.76â€œPassage Know-Howâ€ means all Know-How Controlled by Passage or any of its Affiliates as of the Effective Date that is necessary to Develop, Manufacture or Commercialize the Licensed Compound for the Indication other than any Licensed UPenn Know-How.1.77â€œPassage Technologyâ€ means the Licensed Know-How and Licensed Patents.10â€‹â€‹1.78â€œPatent Right(s)â€ means (a) patents and patent applications, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part, reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing, and (b) all official correspondence relating to the foregoing.1.79â€œPatent Term Extensionâ€ has the meaning set forth in Section 8.3.1.80â€œPersonâ€ means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.1.81â€œPersonal Dataâ€ has the meaning set forth in Section 9.3.1.1.82â€œPhase 1 Studyâ€

means a clinical study of a drug candidate in human patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. Â§312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. Â The drug candidate can be administered to patients as a single agent or in combination with other investigational or marketed agents.1.83â€œPhase 1/2 Studyâ€ means a clinical study of a drug candidate in diseased human patients that satisfies the requirements of a Phase 1 Study and a Phase 2 Study.1.84â€œPhase 2 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. Â§312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States, including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. Â§312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. Â§312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Clinical Study (e.g., a Phase 1/2 Study). Â The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.85â€œPhase 3 Studyâ€ means a clinical study of a drug candidate in human patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. Â The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.86â€œPHS Actâ€ means the United States Public Health Service Act, as amended.1.87â€œPricing and Reimbursement Approvalâ€ means, in a country or other jurisdiction where the Governmental Bodies of such country or jurisdiction approve or determine the price that 11â€‹â€‹can be charged for a pharmaceutical or biological product in such country or jurisdiction, or that can be reimbursed by Governmental Bodies for such product in such country or jurisdiction, (a) the approval, agreement, determination, or decision by the relevant Governmental Bodies establishing the price that can be legally charged to consumers for such product in such country or jurisdiction, or (b) the approval, agreement, determination, or decision by the relevant Governmental Bodies establishing the level of reimbursement that will be reimbursed by Governmental Bodies for such product in such country or jurisdiction.1.88â€œProgram Regulatory Materialsâ€ means any and all Regulatory Materials specific to the Licensed Products that are Controlled by Gemma or any of its Affiliates on or after the Effective Date (including, without limitation, the Regulatory Materials transferred from Passage to Gemma pursuant to the Transition Services Agreement).1.89â€œProgress Reportâ€ has the meaning set forth in Section 6.8.1.1.90â€œProsecute and Maintainâ€ means activities directed to (a) preparing, filing, prosecuting and maintaining Patent Rights, (b) managing and settling any interference, opposition, re-issue, reexamination, supplemental examination, invalidation (including inter partes or post-grant review proceedings), revocation, nullification or cancellation proceeding relating to the foregoing, but excluding managing and settling the defense of challenges to Patent Rights in a declaratory judgment action or as part a counterclaim in an infringement proceeding.1.91â€œQualified Financingâ€ means the next financing, or series of financings, after the Effective Date in which Gemma receives at least [*] in the aggregate, but excluding any non-dilutive financing.1.92â€œRegulatory Approvalâ€ means, with respect to a pharmaceutical or biological product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use, marketing, and sale of such pharmaceutical or biological product in such jurisdiction in accordance with Laws. Â â€œRegulatory Approvalâ€ does not include authorization by a Regulatory Authority to conduct named patient, compassionate use, or other similar activities.1.93â€œRegulatory Authorityâ€ means any Governmental Body, including the FDA, or EMA, or any successor agency thereto, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical or biological product in any country.1.94â€œRegulatory Exclusivityâ€ means, with respect to a given pharmaceutical or biological product and a given country or other jurisdiction, a period of exclusivity (other than exclusivity due to Patent Rights) granted or afforded under Law or by a Regulatory Authority in such country or other jurisdiction that prevents the Regulatory Approval or marketing of any Generic Product of such product in such country, such as new chemical entity, orphan drug or pediatric exclusivity granted or afforded pursuant to the FD&C Act.1.95â€œRegulatory Materialsâ€ means all (a) applications (including all INDs, MAAs and applications for Pricing and Reimbursement Approval), registrations, licenses, authorizations and approvals (including Regulatory Approvals and Pricing and Reimbursement Approvals), (b) 12â€‹â€‹correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files, (c) supplements or changes to any of the foregoing, and (d) clinical and other data, including Clinical Study data, contained or relied upon in any of the foregoing.1.96â€œRegulatory Submissionsâ€ means all Regulatory Materials submitted to a Regulatory Authority in support of the Development, Manufacture or Commercialization of a pharmaceutical or biological product.1.97â€œResearch Programâ€ means the development program for Licensed Products in and for the Indication in the Field of Use to be conducted by Gemma hereunder in accordance with the applicable development plan therefor.1.98â€œRoyaltyâ€ has the meaning set forth in Section 5.4.1.1.99â€œRoyalty Termâ€ means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period beginning on the First Commercial Sale of such Licensed Product in such country and continuing until the latest of: (a) the expiration of the last Valid Claim of the last Licensed UPenn Patent that Covers such Licensed Product in such country, (b) ten (10) years after the First Commercial Sale of such Licensed Product in such country, and (c) termination or expiration of all Regulatory Exclusivities for such Licensed Product in such country.1.100â€œSaleâ€ means any transaction for which consideration is received or invoiced by Gemma, its Affiliates or Sublicensees for sale, use, lease, transfer, or other disposition of a Licensed Product to or for the benefit of a Third Party. Â For clarity, sale, use, lease, transfer, or other disposition of a Licensed Product by Gemma or any of its Affiliates or Sublicensees to another of these entities for resale (or other disposition) by such entity to a Third Party shall not be deemed a Sale.1.101â€œSales Milestone Eventâ€ has the meaning set forth in Section 5.3.1.102â€œSales Milestone Paymentâ€ has the meaning set forth in Section 5.3.1.103â€œSDR Reportâ€ has the meaning set forth in Section 2.3.2.1.104â€œSecurities Regulationâ€ has the meaning set forth in Section 7.5.2.1.105â€œSecurities Regulatorâ€ has the meaning set forth in Section 7.5.2.1.106â€œSegregateâ€ means, with respect to a Competing Product, to use reasonable efforts to segregate the Development, Manufacturing and Commercialization of the Competing Product from the Development, Manufacturing and Commercialization of a Licensed Product, including [*]; provided that applicable personnel within a Partyâ€™s (or its Affiliatesâ€™) financial functions may review financial information with respect to the Competing Product as necessary to comply with its financial oversight and reporting obligations.1.107â€œSpecified Obligationsâ€ means the licenses, options, and obligations that Passage 13â€‹â€‹or Penn has granted or owes to a Third Party that are identified in ExhibitÂ A, [*].1.108â€œSubcontractorâ€ has the meaning set forth in Section 2.4.1.109â€œSublicense Documentsâ€ means any and all agreements, amendments or written understandings entered into with a Sublicensee (including any of its Affiliates) that are directly or indirectly related to a Sublicense, Passage Technology, or Licensed Product. Â For clarity, a development agreement or distribution agreement for a Licensed Product is a Sublicense Document.1.110â€œSublicenseeâ€ means a Person (including any Affiliate) to which a Sublicense, including sub-Sublicensees, is granted pursuant to the terms of Section 2.3.1.1.111â€œTaxâ€ means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body.1.112â€œTermâ€ has the meaning set forth in Section 11.1.1.113â€œTerritoryâ€ means worldwide.1.114â€œThird Partyâ€ means any Person, other than a Party or an Affiliate of a Party.1.115â€œThird Party Claimâ€ has the meaning set forth in Section 10.1.1.1.116â€œThird Party Infringement Claimâ€ has the meaning set forth in Section 8.7.1.1.117â€œTransition Services Agreementâ€ means that certain transition services agreement to be executed by the Parties as of the Effective Date.1.118â€œUnited Statesâ€ or â€œUSâ€ means the United States of America, its territories and possessions.1.119â€œUPenn Agreementâ€ has the meaning set forth in the recitals.1.120â€œUPenn Letter Agreementsâ€ means (a) that certain letter agreement between Passage and Penn dated [*], and (b) that certain letter agreement between Passage and Penn dated [*].1.121â€œUPenn Patentsâ€ means all Patent Rights Controlled by Passage or any of its Affiliates that have been licensed to Passage under the UPenn Agreement and that are related to the Indication. Â The UPenn Patents existing as of the Effective Date are listed on Schedule 1.121 hereto.1.122â€œUPenn Know-Howâ€ means all Know-How Controlled by Passage or any of its Affiliates that have been licensed to Passage under the UPenn Agreement and that is related to the Indication.14â€‹â€‹1.123â€œUS Bankruptcy Codeâ€ has the meaning set forth in Section 11.4.2.1.124â€œUSD,â€ â€œDollars,â€ or â€œ$â€ means United States dollars.1.125â€œValid Claimâ€ means, with respect to Patent Rights, a claim of (a) an issued and unexpired patent in such Patent Rights which claim has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no further appeal can be taken or has been taken within the time allowed for appeal, and has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer; or (b) a pending patent application (that has been pending for no more than [*] from the filing date of such application) that is included in such Patent Rights which was filed and is being prosecuted in good faith, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.Article 2â€‹LICENSE2.1Exclusive License to Gemma. Â Subject to the terms and conditions of this Agreement, during the Term, Passage, on behalf of itself and its Affiliates, hereby grants to Gemma an exclusive (even as to Passage and its Affiliates), transferable (solely in accordance with SectionÂ 12.1), sublicensable (solely in accordance with SectionÂ 2.3), royalty-bearing license under the Passage Technology to make, have made, use, sell, offer for sale and import the Licensed Products for the Indication in the Field of Use in the Territory; provided that, to the extent any Passage Technology is non-exclusively licensed to Passage by Penn (â€œNon-Exclusively Licensed Penn IPâ€), the license granted by Passage to Gemma under such Non-Exclusively Licensed Penn IP shall be exclusive solely with respect to Passageâ€™s interest in such Non-Exclusively Licensed Penn IP (the â€œLicenseâ€).2.2Retained Rights. Â Notwithstanding the exclusive nature of the License, Passage retains the rights to practice the Passage Technology solely to perform its obligations under this Agreement and the UPenn Agreement.2.3Right to Sublicense.2.3.1Passage grants to Gemma the right to grant sublicenses, in whole or in part, under the License (each, a â€œSublicenseâ€) subject to the terms and conditions of this Agreement and specifically this Section 2.3. Â The term â€œSublicenseâ€ shall include any grant of rights under the License by a Sublicensee to any downstream Third Party, provided such downstream Third Party shall also be considered a Sublicensee for purposes of this Agreement.2.3.2All Sublicenses will (a) be issued in writing, (b) to the extent applicable, include all of the rights of Passage and require the performance of obligations due to Passage (and, if applicable, Penn and the U.S. Government under 35 U.S.C. Â§Â§200-212) contained in this Agreement, and (c) include no less than the following terms and conditions:(a)Reasonable record keeping, audit and reporting obligations sufficient to enable Gemma and Passage to reasonably verify the payments due to Gemma, Penn and Passage under such Sublicense and to reasonably monitor such Sublicenseeâ€™s progress in 15â€‹â€‹Developing or Commercializing Licensed Product; provided that such obligations shall be no less stringent that those provided in this Agreement for Gemma.(b)Infringement and enforcement provisions that do not conflict with the restrictions and procedural requirements imposed on Gemma and do not provide greater rights to Sublicensee than as provided in Section 8.6.(c)Confidentiality provisions with respect to Confidential Information of Passage and Penn consistent with the restrictions on Gemma in Article 7 of this Agreement.(d)Covenants by Sublicensee that are equivalent to those made by Gemma in Sections 9.3 and 9.5.(e)A requirement of indemnification of Passage and Penn by Sublicensee that is equivalent to the indemnification of Passage by Gemma under Sections 10.1.1 and 10.1.2 of this Agreement and of Penn by Gemma under Section 10.1.3 of this Agreement.(f)A requirement of obtaining and maintaining insurance by Sublicensee that is equivalent to the insurance requirements of Gemma under Section 10.4 of this Agreement, including coverage under such insurance of Passage and Penn as provided in Section 10.4.(g)Restriction on use of Passageâ€™s and Pennâ€™s names, etc. consistent with Section 7.6 of this Agreement.(h)A requirement of antidiscrimination by Sublicensee no less stringent than that provided in Section 12.3 of this Agreement.(i)A requirement that Passage and Penn are third party beneficiaries of such Sublicense.Any Sublicense that does not include all of the terms and conditions set forth in this Section 2.3.2 or which is not issued in accordance with the terms and conditions set forth in this Section 2.3, shall be considered null and void with no further notice from Passage unless separately approved by Passage in writing.Within [*] after the execution of a Sublicense Document, Gemma shall provide a complete and accurate copy of such Sublicense Document to Passage, in the English Language. Â Passageâ€™s receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Passage or obligation of Gemma under this Agreement.Gemma and its Sublicensees shall provide an annual Sublicense Development Report on or before [*] of each year during the Term (â€œSDR Reportâ€), a form of which is attached hereto as ExhibitÂ B.2.4Right to Subcontract. Â Each Party may subcontract the performance of any of its obligations under this Agreement to one or more Third Party subcontractors engaged for the purpose of Development, Manufacture or Commercialization of the Licensed Products as set forth 16â€‹â€‹herein (each such Third Party a â€œSubcontractorâ€). Â All such Subcontractors shall be subject to a written agreement that is consistent with the applicable terms and conditions of this Agreement and must meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity, including entering into such Partyâ€™s standard nondisclosure agreement consistent with Article 7 and the ownership and management of intellectual property rights. Â Each Party shall remain responsible and liable to the other Party for the performance of all Subcontractors to the same extent as if such activities were conducted by such Party. Â Any Party engaging a Subcontractor hereunder will remain responsible and obligated for such activities and will not grant rights to such Subcontractor that interfere with the rights of the other Party under this Agreement.2.5Right of Access and Reference. Â 2.5.1Gemma hereby grants to Passage a right of reference to all Program Regulatory Materials in the Territory solely for [*].2.5.2Passage hereby grants to Gemma a right of reference to all Regulatory Materials Controlled by Passage or its Affiliates in the Territory solely for [*]. 2.5.3Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 2.5, including providing a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of access and reference.2.6No Implied Licenses. Â Except as expressly set forth in this Agreement, neither Party nor its Affiliates, by virtue of this Agreement, shall acquire any license, right or other interest, whether by implication or otherwise, in or to any Know-How, Patent Rights, Regulatory Materials, Materials or other intellectual property rights owned or controlled by the other Party or its Affiliates.2.7Upstream License. Â To the extent any Passage Technology licensed to Gemma pursuant to the License includes a sublicense to Patent Rights or Know-How licensed to Passage or its Affiliates under the UPenn Agreement, the Parties acknowledge and agree that such sublicensed Passage Technology is subject to the terms and conditions of the UPenn Agreement. Â Gemma agrees to abide by all terms and conditions of the UPenn Agreement as they relate to Gemma as a Sublicensee under such agreement and notwithstanding anything in this Agreement to the contrary, in the event of any conflict between the terms hereof and the terms of the UPenn Agreement as they relate to Gemma as a Sublicensee under the UPenn Agreement, the terms of the UPenn Agreement shall govern. Â Gemma shall timely take all actions reasonably necessary or requested by Passage, including timely providing to Passage all information reasonably necessary, for Passage to comply with its obligations under the UPenn Agreement. Â Without limiting the foregoing, Gemma shall provide to Passage the information necessary for Passage to comply with any royalty or milestone reporting obligations under the UPenn Agreement. Without limiting Section 5.8, Gemma shall be solely responsible for [*] of all amounts payable by Passage under the UPenn Agreement on and after the Effective Date (including milestone payments and royalties) incurred as a result of Gemmaâ€™s exercise of its rights under this Agreement.17â€‹â€‹2.7.1Penn Retained Rights. Â Without limiting Section 2.7 and notwithstanding the exclusive nature of the License, Gemma acknowledges and agrees that the License is subject to Pennâ€™s rights under the UPenn Agreement, including:(a)Pennâ€™s right to (i) conduct educational, research, clinical activities, and patient care activities itself, including, but not limited to sponsored research, and (ii) authorize non-commercial Third Parties to conduct educational, research and clinical activities and patient care activities, all as more fully described in the UPenn Agreement; and(b)any applicable requirement, order, written request, or decree by a Regulatory Authority to Penn to make any Patent Rights, Know-How, or Materials available to a Third Party on a non-exclusive basis.2.7.2U.S. Government Rights. Â Without limiting Section 2.7 and notwithstanding the exclusive nature of the License, Gemma acknowledges and agrees that the License is expressly subject to all applicable provisions of any license to the United States Government executed by Penn and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. Â§Â§200-212, applicable governmental implementing regulations, and U.S. Government sponsored research agreement or other guidelines, including that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States.2.8Third Party Licenses. Â Gemma shall have the right, in its sole discretion, to negotiate and obtain licenses or other rights to Third Party Know-How, Patent Rights or other rights in connection with its Development, Manufacture or Commercialization of the Licensed Products in the Territory, and, if applicable, Section 5.4.2(c) shall apply to any amounts payable to such Third Party with respect to any such license or right.Article 3â€‹EXCLUSIVITY3.1Exclusivity. Â During the period of [*] after the Effective Date (the â€œExclusivity

Periodâ€), Gemma will not, and will ensure that its Affiliates and Sublicensees do not (a) [*], or (b) [*], in each case (a) and (b), other than Commercialization of the Licensed Products in accordance with the terms of this Agreement.3.2Exception for Change of Control. Â Notwithstanding Section 3.1, if: 3.2.1Gemma or any of its Affiliates acquires any Competing Product or the rights to research, develop, manufacture or commercialize any Competing Product anywhere in the Territory in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction), then such acquisition, and the research, development, manufacture or commercialization of such Competing Product thereafter, shall not constitute a breach of Section 3.1 if Gemma or such Affiliate, as applicable, Divests such Competing Product within [*] after the closing of such acquisition and at all times Segregates such Competing Product prior to such Divestiture; and18â€‹â€‹3.2.2Gemma undergoes a Change of Control and the Acquiror (or its Affiliate) is at the time of the closing of such Change of Control researching, developing, manufacturing or commercializing a Competing Product anywhere in the Territory, then such Change of Control, and the research, development, manufacture or commercialization of such Competing Product by such Acquiror or its Affiliate, shall not constitute a breach of Section 3.1 if such Acquiror or its Affiliate Divests such Competing Product within [*] after the closing of such Change of Control and at all times Segregates such Competing Product prior to such Divestiture.Article 4â€‹GOVERNANCE4.1Alliance Managers. Â Each Party will appoint a representative to act as its alliance manager under this Agreement (each, an â€œAlliance Managerâ€). Â Each Alliance Manager will be responsible for promoting effective communication between the Parties and shall be the primary point of contact between the Parties.4.2Cooperation with UPenn Agreement Committees.4.2.1General. Â During the Term, Gemma shall provide Passage with all reasonable assistance, at Passageâ€™s request, for Passage to respond to any request by Penn or under any committee formed under the UPenn Agreement, including preparing relevant reports and responses, providing access to relevant documents, and other evidence, and making its employees reasonably available during business hours as necessary, in each case at Gemmaâ€™s cost and expense. Â Passage shall use Commercially Reasonable Efforts to seek Gemmaâ€™s comments with respect to any such request (including to the extent permissible, seeking a representative of Gemmaâ€™s attendance at any such committee meeting and discussing in good faith any materials submitted thereto with respect to the Licensed Products).4.2.2Updates to Existing JSCs. Â Without limiting Section 4.2.1, during the Term, upon Passageâ€™s reasonable request, Gemma shall provide an update to the development plan delivered under Section 6.1 for the Licensed Products describing the status of the clinical development thereof, for Passageâ€™s and Pennâ€™s review.Article 5â€‹PAYMENTS5.1Product Supply; Upfront Fee. As partial consideration for the License and other rights granted by Passage to Gemma herein, and in exchange for Passageâ€™s supply of product for the conduct of a Clinical Study for a Licensed Product by Gemma or its designee, Gemma shall pay to Passage (a) [*], and (b) [*].5.2Development and Regulatory Milestones. Â Upon the first achievement by Gemma, its Affiliate or a Sublicensee of each development and regulatory milestone event set forth in the table below (each a â€œDevelopment Milestone Eventâ€), Gemma shall make the corresponding one-time, non-refundable, non-creditable payment set forth in the table below (each a â€œDevelopment Milestone Paymentâ€) to Passage in accordance with Section 5.5.1.Development Milestone EventDevelopment Milestone 19â€‹â€‹Payment (USD)[*][*][*][*]Total[*]If any of the above Development Milestone Events are skipped (such that a later Development Milestone Payment becomes due and payable before an earlier Development Milestone Payment), then the skipped Development Milestone Event(s) will be deemed to have been achieved upon the achievement of the subsequent Development Milestone Event, and the Development Milestone Payment(s) corresponding to such skipped Development Milestone Event(s) shall be due and payable at the same time as the subsequent Development Milestone Event.5.3Sales Milestones. Â Upon the first achievement of each sales-based milestone event set forth in the table below (each, a â€œSales Milestone Eventâ€), Gemma shall make the corresponding one-time, non-refundable, non-creditable payment set forth in the table below (each a â€œSales Milestone Paymentâ€) to Passage in accordance with Section 5.5.1.Sales Milestone EventSales Milestone Payment (USD)[*][*][*][*][*][*]Total[*]Each of the foregoing Sales Milestone Payments in this Section 5.3 shall be payable a maximum of one (1) time hereunder regardless of the number of times the applicable Sales Milestone Event is achieved. Â For the avoidance of doubt, the aggregate maximum amount payable by Gemma under this Agreement pursuant to this Section 5.3 is [*]. Â In the event that in a given Calendar Year more than one (1) Sales Milestone Event is achieved, Gemma shall pay to Passage the Sales Milestone Payment with respect to each such Sales Milestone Event.5.4Royalty Payments.5.4.1Royalty Payments for Licensed Products. Â Subject to the remainder of this Section 5.4, on a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product, Gemma shall pay Passage a [*] royalty on aggregate annual Net Sales of such Licensed Product in the Territory (the â€œRoyaltyâ€), calculated by multiplying [*] by the aggregate annual Net Sales of all Licensed Products in the Territory. Â Such payments, and associated reports, shall be made in accordance with Section 5.5.2.5.4.2Royalty Reductions.(a)No Valid Claim. On a country-by-country basis, if at any time during the Royalty Term for a Licensed Product in such country there is no Valid Claim of the 20â€‹â€‹Licensed UPenn Patents that Covers such Licensed Product in such country and such Licensed Product is not subject to Regulatory Exclusivity, then (i) the royalty rate set forth in Section 5.4.1 for such Licensed Product shall be permanently reduced in such country by [*] for the remainder of such Royalty Term, and (ii) no Royalty at all will apply to such Licensed Product [*].(b)Compulsory License. Â In the event that Gemma or Passage receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. Â If any Third Party obtains a Compulsory License in any country, then: (i) Gemma or Passage (whoever has first notice) shall promptly notify the other Party; and (ii) beginning as of the date the Third Party obtained such Compulsory License in such country, the Royalty rate payable under Section 5.4.1 to Passage for Net Sales in such country will be adjusted to equal any lower Royalty rate granted to such Third Party for such country with respect to the sales, use, lease, transfer or other disposition of such Licensed Product by such Third Party therein.(c)Third Party Payments. If, after the Effective Date, Gemma determines upon the advice of outside intellectual property counsel that a license to Patent Rights from a Third Party is reasonably necessary to develop, commercialize, or manufacture a Licensed Product in a particular country, Gemma may obtain such Third Party license to such Patent Rights. Â Gemma may deduct from any Royalty payments due to Passage under Section 5.4.1 an amount equal to [*] of any Royalty paid by Gemma to a Third Party on Sales of a particular Licensed Product in a particular country during a Calendar Quarter under a Third Party license obtained by Gemma for such country, pursuant to this Section 5.4.2(b).(d)Generic Product. In the event that one or more Generic Product(s) with respect to a particular Licensed Product enter(s) the market in a particular country, and such Generic Product(s) in the aggregate have a market share of [*] or more in that country, Gemma may reduce the Royalty payments for Sales of such Licensed Product in such country by [*]; provided that if Gemma reduces the Royalty payments under this Section 5.4.2(d), Gemma shall resume making Royalty payments without reduction under this Section 5.4.2(d) as of the earlier of (a) no Generic Product being sold for at least [*] in such country, and (b) a court of competent jurisdiction determines that a Valid Claim of a Licensed UPenn Patent is valid and infringed by such Generic Product in such country.(e)Cumulative Reductions Floor. In no event will the amount of Royalties due to Passage for a Licensed Product in any given Calendar Quarter be reduced as a result of the reductions set forth in Sections 5.4.2(c) and 5.4.2(d) (cumulatively) by more than [*] of the amount that otherwise would have been due and payable to Passage in such Calendar Quarter for such Licensed Product.5.4.3Royalty Payments. Â Gemma shall pay Royalties owed to Passage on a Calendar Quarter basis on or before the following dates:(a)[*] for any Sales that took place in the Calendar Quarter ending DecemberÂ 31, of the prior Calendar Year;(b)[*] for any Sales that took place in the Calendar Quarter ending MarchÂ 31 of such Calendar Year;21â€‹â€‹(c)[*] for any Sales that took place in the Calendar Quarter ending JuneÂ 30 of such Calendar Year; and(d)[*] for any Sales that took place in the Calendar Quarter ending SeptemberÂ 30 of such Calendar Year.5.5Payment Terms.5.5.1Milestone Payments. Â Gemma shall promptly notify Passage in writing upon the occurrence of a Development Milestone Event or Sales Milestone Event and Gemma shall pay Passage in full the corresponding non-refundable Development Milestone Payment or Sales Milestone Payment within [*] after such occurrence.5.5.2Royalty Reports. Â Within [*] after the end of each Calendar Quarter, Gemma shall deliver to Passage (or at Passageâ€™s written direction, Penn) a report (â€œFinancial Reportâ€) setting out all details necessary to calculate the Royalty due under this Article 5 for such Calendar Quarter, including:(a)[*];(b)Gross sales and Net Sales of each Licensed Product made by Gemma, its Affiliates and Sublicensees (including sub-Sublicensees);(c)Royalties;(d)The method and currency exchange rates (if any) used to calculate the Royalties;(e)A specification of all deductions and their dollar value that were taken to calculate Net Sales;(f)A list of all countries in which Licensed Product is being manufactured (on a Licensed Product-by-Licensed Product basis); and(g)The date of First Commercial Sale in the United States (this need only be reported in the first Financial Report following such First Commercial Sale in the United States).Each Financial Report shall be in the form of the sample report attached hereto as ExhibitÂ C.5.6Payment Currency; Exchange Rate; Offset. Â All payments to be made under this Agreement shall be made in USD. Â Payments to a Party shall be made by electronic wire transfer of immediately available funds to the account of the other Party, as designated in writing to the paying Party. Â If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the average of the rates quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter for which such payment is made. Â Gemma shall not have the right to offset any payment that is owed by Gemma 22â€‹â€‹to Passage but not yet paid against any payments owed by Passage to Gemma under this Agreement.5.7Late Payments. Â Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [*] per month or (b) the maximum rate permitted by Law; in each case calculated on the number of days such payment is delinquent, compounded monthly. Â In the event of a default in payment of any payment owing under the terms of this Agreement, and if it becomes necessary for Passage to undertake legal action to collect said payment, Gemma shall pay reasonable, documented legal fees and costs incurred in connection therewith.5.8Payments to Third Parties. Â Gemma shall be solely responsible for [*] of all amounts payable by Passage under the UPenn Agreement on and after the Effective Date (including milestone payments and royalties) incurred as a result of Gemmaâ€™s exercise of its rights under this Agreement. Â Gemma shall pay such amounts to Passage in accordance with this Article 5 (unless otherwise directed by Passage in writing to make payments directly to such licensor), in each case, no later than [*] prior to the date on which the applicable amount is due and payable by Passage under the UPenn Agreement. Â Without limiting the foregoing, Gemma shall promptly (but in any event not more than [*] thereafter) provide notice to Passage upon the achievement (by Gemma, its Affiliates or Sublicensees) of any of the third party milestones set forth in ExhibitÂ D and pay the corresponding milestone amount owed under the UPenn Agreement, as provided by Passage to Gemma, to Passage (unless otherwise directed by Passage in writing to make payments directly to Penn) no later than [*] following the achievement of such milestone. Â At the request of Gemma, Passage shall use Commercially Reasonable Efforts to seek applicable and available reductions of any royalties owed under the UPenn Agreement.5.9Accounting. Â Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.5.10Records and Audit Rights.5.10.1Records. Â Gemma will keep accurate books and records of all Licensed Products developed, manufactured, used, or sold and all Sublicenses, collaboration agreements and joint venture agreements entered into by Gemma that involve Passage Technology. Â Gemma will preserve these books and records for at least [*] from the date of the Financial Report to which they pertain. Â Upon reasonable notice, key personnel, books, and records will be made reasonably available and will be open to examination by representatives or agents of Passage or Penn during regular office hours to determine their accuracy and assess Gemmaâ€™s compliance with the terms of this Agreement and the UPenn Agreement; provided that Gemma shall not have an obligation to provide access more than once in any given [*] period to Passage.5.10.2Audit. Â In addition to the right of Passage and Penn to examine the books and records and interview key personnel as provided in Section 5.10.1, Passage or Penn (each an â€œAuditing Partyâ€), at its own cost, through an independent auditor reasonably acceptable to Gemma (and who has executed an appropriate confidentiality agreement reasonably acceptable to Gemma that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to the Auditing Party), may inspect and audit the relevant 23â€‹â€‹records of Gemma pertaining to the calculation of any payments due hereunder (including any Development Milestone Payments, Sales Milestone Payments, or Royalties). Â Gemma shall provide such auditors with access to the records during reasonable business hours. Â Such access need not be given to any such set of records more often than once each year for a given Auditing Party or more than [*] after the date of any report to be audited. Â The Auditing Party shall provide Gemma with written notice of its election to inspect and audit the records related to the payments due hereunder not less than [*] prior to the proposed date of review of Gemmaâ€™s records by the Auditing Partyâ€™s auditors. Â Should the auditor find any underpayment by Gemma, Gemma shall (a) promptly pay Passage (or at Passageâ€™s written direction, Penn) the amount of such underpayment; (b) shall reimburse the Auditing Party for the cost of the audit, if such underpayment equals or exceeds the higher of (i) [*] or (ii) [*] of all payments paid to Passage (or with respect to Penn, the amount owed under the UPenn Agreement) during the time period audited; and (c) provide such auditors with an audit right exercisable within [*] after such Auditing Party receives the audit report. Â If the auditor finds overpayment by Gemma, then Gemma shall have the right to deduct the overpayment from any future income due to Passage (or with respect to Penn, the amount owed under the UPenn Agreement) or, if no such future payments are due hereunder (or with respect to Penn, future payments due under the UPenn Agreement) shall refund the overpayment to Gemma within [*] after the Auditing Party receives the audit report; provided that to the extent any amounts owed to Gemma relate to the UPenn Agreement, Passage shall refund the overpayment to Gemma within [*] after receiving payment for such overpayment from Penn, if not paid directly to Gemma.5.11Taxes. All payments made by Gemma to Passage (or Passageâ€™s designee) under this Agreement shall be made free and clear of and without any deduction for or on account of any Taxes on or with respect to such payments.5.12Blocked Currency. Â If due to Law in a country or other jurisdiction in the Territory, conversion into USD or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Gemma shall promptly notify Passage and, thereafter, amounts accrued in such country or other jurisdiction under this Article 5 (other than Section 5.8) shall be paid to Passage (or its designee) in such country or other jurisdiction in local currency by deposit in a local bank designated by Passage and to the credit of Passage, unless the Parties otherwise agree. For clarity, [*].Article 6â€‹DEVELOPMENT AND COMMERCIALIZATION6.1Development Plan. Gemma shall provide Passage or its designee with a development plan (or updated development plan) no later than [*] of each year during the Term. Â The development plan shall include a timeline for detailed activities to be conducted by Gemma, its Affiliates and Sublicensees, and Gemma shall provide Passage with [*] progress reports regarding achievements and activities under such development plan. Â Subject to Section 6.2, [*].6.2Clinical Development. Â Gemma shall have the first right to sponsor all clinical activities and lead regulatory interactions for the Licensed Products, and will be solely responsible for the associated costs of such Development. Â Gemma will consider in good faith using Penn as a study site for one or more Clinical Studies where Penn can reasonably demonstrate that Pennâ€™s 24â€‹â€‹capabilities and costs are reasonably comparable to other potential study sites. Â If Penn (in its sole discretion) is willing and able to conduct a Clinical Study for a Licensed Product developed under the Research Program, the Parties and Penn will negotiate a separate clinical trial agreement and a separate clinical trial budget prior to initiation of such Clinical Study; provided that any such study shall be at Gemmaâ€™s cost and expense.6.3Commercialization. Gemma will have sole responsibility for and sole decision-making over the Commercialization of the Licensed Products for the Indication in the Field of Use, and will be solely responsible for the associated costs of such Commercialization.6.4Manufacturing. Â Gemma will have sole responsibility for and sole decision-making authority over all Manufacturing of the Licensed Products for the Indication in the Field of Use.6.5Regulatory. Â Gemma will have responsibility for and decision-making over regulatory activities for the Licensed Products for the Indication in the Field of Use. Â Gemma will have the right to conduct all communications with Regulatory Authorities, including all meetings, conferences, and discussions (including advisory committee meetings), with regard to Licensed Products for the Indication in the Field of Use; provided, [*]. Â Gemma will lead and have control over preparing and submitting all Regulatory Submissions related to the Licensed Products for the Indication in the Field of Use, including all MAAs, provided, however, that Gemma shall provide Passage (or at Passageâ€™s written request, Penn) with copies of all such applications prior to submission, to the extent such submission includes any Confidential Information of Passage. Â Gemma will own any and all Regulatory Materials, Regulatory Submissions (including INDs), and Regulatory Approvals related to the Licensed Products for the Indication in the Field of Use, which will be held in the name of Gemma or its designees.6.6General Diligence. Gemma will use Commercially Reasonable Efforts to actively Develop, obtain Regulatory Approval for and Commercialize at least one Licensed Product for the Indication in the Field of Use.6.7Diligence Events.6.7.1General. Â Gemma shall achieve each of the diligence events set forth in ExhibitÂ E (each a â€œDiligence Eventâ€) by the corresponding achievement date (each a â€œAchievement Dateâ€). Â Gemma acknowledges that the achievement of each Diligence Event by the corresponding achievement date is a condition of the UPenn Agreement. Â The timeline for each Achievement Date is based on the assumption that Development and Commercialization of the Licensed Products does not encounter material regulatory or other delays for reasons outside of Gemmaâ€™s reasonable control. Â Where such circumstances exist, Passage agrees to negotiate in good faith with Gemma and Penn (on Gemmaâ€™s behalf), upon Gemmaâ€™s written request and provided such request is made at least [*] prior to the Achievement Date for a Diligence Event, an extension of the Achievement Date for a Diligence Event for such Licensed Products as reasonably requested by Gemma. Â If the Parties and Penn have not agreed on a requested extension within [*] of Passageâ€™s notice to Penn of such request, then upon either

Gemmaâ€™s or Pennâ€™s written request, Passage and Penn [*]. Â For clarity, [*].25â€‹â€‹6.7.2Review. Â Gemma acknowledges that if, following a review requested by Penn under Section 4.2.2, Penn in good faith reasonably believes that Gemma has not materially funded any activities to advance the Development of the Licensed Products during any [*], Penn may submit such matter for arbitration by an arbitrator selected in accordance with Section 6.7.1 to determine whether Gemma has failed to materially fund any such activities. Â The Parties shall use Commercially Reasonable Efforts to cooperate with each other with respect to any such arbitration (including to the extent permissible, seeking a representative of Gemmaâ€™s attendance at any hearing and discussing in good faith any materials submitted thereto with respect to the Licensed Products). Â All costs and expenses incurred by Passage with respect to such arbitration (including its reasonable legal fees) shall be reimbursed by Gemma within [*] of an invoice therefor. Â Gemma acknowledges and agrees that, if (i) the arbitrator finds that Gemma (on behalf of Passage) has failed to materially fund any such activities as set forth above, and (ii) Gemma does not cure such failure to materially fund within [*] of the arbitratorâ€™s determination, then, notwithstanding anything in this Agreement to the contrary, Passage will have the right to terminate this Agreement with immediate effect upon written notice to Gemma.6.8Progress Reports.6.8.1Prior to the First Commercial Sale of a Licensed Product, on an annual basis but in no event later than [*] of each Calendar Year, Gemma shall submit to Passage (or at Passageâ€™s written direction, Penn) a progress report (each, a â€œProgress Reportâ€) covering Gemmaâ€™s (and any Affiliatesâ€™ and Sublicenseesâ€™) activities related to the Development of all Licensed Products and the obtaining of Regulatory Approvals necessary for Commercialization of Licensed Products.6.8.2Each Progress Report must include all of the following for each annual period:(a)Summary of material Development activities;(b)Summary of material Commercialization activities;(c)Identification of filings for Regulatory Approval and other material correspondence with Regulatory Authorities;(d)An updated SDR Report listing any and all Sublicenses granted by Gemma; and(e)The names and addresses of all Sublicensees, and a current and valid phone number and e-mail address for a principal point of contact at each such Sublicensee who is responsible for administering the Sublicensee.Article 7â€‹CONFIDENTIALITY7.1Confidential Information. Â For purposes of this Agreement, â€œConfidential Informationâ€ of a Party means any and all confidential or proprietary information, data, or materials, including all Know-How and other scientific, pre-clinical, clinical, regulatory, 26â€‹â€‹manufacturing, marketing, financial and commercial information or data, whether or not patentable and in any form (written, oral, photographic, electronic, magnetic, or otherwise), including information of Third Parties, that such Party (or an Affiliate or representative of such Party) discloses or otherwise makes available to the other Party (or to an Affiliate or representative of the other Party) in connection with this Agreement. Â The Passage Technology shall be the Confidential Information of Passage, and the terms and conditions of this Agreement shall be the Confidential Information of both Parties.7.2Duty of Confidence; Exceptions. Â Each Party agrees that, during the Term and for a period of [*] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (including for the exercise of the rights and licenses granted to such Party hereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. Â The foregoing confidentiality and non-use obligations shall not apply with respect to any information that the receiving Party can demonstrate by competent written proof:7.2.1was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed by the disclosing Party to the receiving Party, or was otherwise developed independently by or for the receiving Party without use of or reference to the disclosing Partyâ€™s Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;7.2.2was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party, as evidenced by written records of the receiving Party;7.2.3became generally available to the public or otherwise part of the public domain after its disclosure other than through any act or omission of the receiving Party in breach of this Agreement; or7.2.4was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.Any combination of features shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.7.3Authorized Disclosures. Â Notwithstanding Section 7.2, the receiving Party may disclose the disclosing Partyâ€™s Confidential Information if and to the extent such disclosure is reasonably necessary in the following instances:7.3.1subject to Section 7.5, to comply with Law;7.3.2to its external attorneys, independent accountants, or financial advisors solely for the purpose of enabling such attorneys, independent accountants, or financial advisors to provide advice to it; and27â€‹â€‹7.3.3to its Affiliates, employees, consultants, and agents and actual or potential Sublicensees (in the case of Gemma), collaborators, actual or potential investors, or contractors, as applicable and as may be needed to exercise its rights or perform its obligations in accordance with the terms of this Agreement;provided that in each of the cases of Sections 7.3.1-7.3.3 such Person is subject to a written agreement containing obligations of confidentiality and non-use at least as stringent as those herein (or without such agreement for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement).Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Partyâ€™s Confidential Information pursuant to SectionsÂ 7.3.1 and 7.3.3, it will, except where impracticable, promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Partyâ€™s efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the other Partyâ€™s expense. Â In any such event, each Party agrees to take all reasonable actions to minimize disclosure of the other Partyâ€™s Confidential Information. Â Any information disclosed pursuant to this Section 7.3 shall remain, subject to Section 7.2, the Confidential Information of the disclosing Party and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 7.7.4Prior Confidentiality Agreements. Â This Agreement supersedes that certain Mutual Confidentiality Agreement between the Parties effective as of [*] (the â€œCDAâ€). Â All information exchanged between the Parties under the CDA shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 7.7.5Public Disclosures; Securities Filings.7.5.1Press Release. Â Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed); provided, however, that (a) neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Securities Regulations, (b) either Party may make subsequent public disclosure of the contents of any such approved press release or other public statement, and (c) Passage shall have the right to make public announcements regarding the achievement of any material events regarding the progress of the Development and Commercialization of a Licensed Product under this Agreement, as well as the achievement of Development Milestone Events or Sales Milestone Events, or the receipt of any payments hereunder.7.5.2Securities Filings. Â Notwithstanding anything herein to the contrary, a Party or its Affiliates may disclose the relevant terms of this Agreement to the extent required or advisable to comply with the rules and regulations promulgated by the US Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory (such rules and regulations â€œSecurities Regulationsâ€ and each such agency a â€œSecurities Regulatorâ€). Â If a 28â€‹â€‹Party is required by Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator, such Party agrees to reasonably consult and coordinate with the other Party with respect to such disclosure and, if applicable, the preparation and submission of a confidential treatment request for this Agreement. Â Notwithstanding the foregoing, if a Party is required by Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator and such Party has (i) promptly notified the other Party in writing of such requirement and any respective timing constraints, (ii) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure, and (iii) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Law or the applicable Securities Regulator. Â If a Party seeks to make a disclosure or filing as set forth in this Section 7.5.2 and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will reasonably consider such comments and use good faith efforts to incorporate such comments in the disclosure or filing; provided that prior to making any such filing of this Agreement, the Parties shall reasonably cooperate and use good faith efforts to agree on a redacted form of this Agreement to be so filed.7.6Use of Names. Â Gemma, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Passage, Penn or any Penn school, organization, employee, student or representative, without the prior written consent of Passage or Penn, as applicable. Â Notwithstanding the foregoing, Gemma may use the name of Passage or Penn in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by Gemma for the purpose of raising financing for the operations of Gemma as related to Licensed Product, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Passage Technology (subject to the provisions of Article 7) have been licensed by Gemma from Passage and sublicensed by Gemma from Penn, and/or to inform a reader of the identity and published credentials of inventors of intellectual property, and (b) any securities reports required to be filed with a Securities Regulator in the US.Article 8â€‹INTELLECTUAL PROPERTY8.1Ownership. Â Inventorship of Arising Know-How and all intellectual property rights therein shall be determined in accordance with principles of inventorship for Patent Rights and other intellectual property under US law, and ownership shall follow inventorship.8.2Patent Prosecution and Maintenance.8.2.1Licensed UPenn Patents. Â Gemma acknowledges that the Prosecution and Maintenance of the Licensed UPenn Patents shall be controlled by Penn. Â Passage shall use Commercially Reasonable Efforts to cooperate with Gemma to provide any comments to such Prosecution and Maintenance of the Licensed UPenn Patents to Penn, as allowable under the UPenn Agreement. Â Gemma will bear all amounts required to be paid to Penn under the UPenn Agreement during the Term for the Prosecution and Maintenance of the Licensed UPenn Patents.29â€‹â€‹8.2.2Gemma Collaboration Patents. Â As between the Parties, Gemma shall have the sole right, but not the obligation, to Prosecute and Maintain the Gemma Collaboration Patents in the Territory, at Gemmaâ€™s cost and expense.8.3Cooperation for Patent Extensions. Â [*].8.4Patent Listings. Â Passage shall have the sole right to list or de-list the UPenn Patents in the FDAâ€™s â€œPurple Bookâ€ or any equivalent thereto in any country in the Territory with respect to the Licensed Products. Â Gemma shall reasonably cooperate with Passage in making or withdrawing any such listing for a UPenn Patent, including executing all necessary documents to implement such patent listing, at its cost and expense.8.5Common Interest Disclosures. Â With regard to any information or opinions exchanged pursuant to this Agreement by the Parties (or their Affiliates) regarding intellectual property owned by Third Parties, the Parties agree that they have a common legal interest in coordinating Prosecution and Maintenance of their respective Patent Rights, as set forth in this Article 8, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Development, Manufacturing or Commercialization of the Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the Development, Manufacturing or Commercialization of the Licensed Products. Â Accordingly, Gemma and Passage agree that all such information and materials obtained by Gemma or Passage from each other will be used solely for purposes of the Partiesâ€™ common legal interests with respect to the conduct of this Agreement. Â All information and materials will be treated as protected by the attorney-client privilege, the work product privilege and any other privilege or immunity that may otherwise be applicable. Â By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Â Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Partyâ€™s prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Party.8.6Patent Enforcement.8.6.1Notice. Â Each Party shall notify the other within [*] after becoming aware of any alleged or threatened infringement by a Third Party of any UPenn Patent or Gemma Collaboration Patent (an â€œInfringement Noticeâ€), which infringement adversely affects or could reasonably be expected to adversely affect the Development, Manufacture or Commercialization of any Licensed Product for the Indication in the Field of Use in the Territory, or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Right (each a â€œCompetitive Infringementâ€).8.6.2Gemma Collaboration Patents. Â As between the Parties, Gemma shall have the sole right, but not the obligation, to enforce the Gemma Collaboration Patents or take any steps to abate an alleged or actual Third Party infringement of any Gemma Collaboration Patent anywhere in the Territory, at Gemmaâ€™s sole cost and expense.30â€‹â€‹8.6.3Licensed UPenn Patents.(a)Notification of Infringement. Â Gemma shall [*] without first obtaining the written consent of Passage, which consent will not be unreasonably withheld, conditioned or delayed. Â If Gemma [*], then Gemmaâ€™s right to request Passage initiate an Enforcement Action under Section 8.6.3(b) below will terminate immediately without the obligation of Passage to provide notice to Gemma. Â Passage and Gemma will use their diligent efforts to cooperate with each other and Penn to terminate such infringement without litigation.(b)Request for Enforcement. Â If the Competitive Infringement of a UPenn Patent has not been abated within [*] following the date the Infringement Notice was provided and during the period in which, and in the jurisdiction where, Passage is exclusively licensed under such infringed UPenn Patent (such UPenn Patent, during such period and in such jurisdiction, the â€œExclusive Penn Patent Rightsâ€), then Gemma may, but no later than [*] following the date of the Infringement Notice, request Passage to institute an Enforcement Action of an Exclusive Penn Patent Right against the infringer. Â Following receipt of such request, Passage shall use [*]. Â Passage shall keep Gemma reasonably informed as to the status of any such Enforcement Action and shall consider in good faith the comments of Gemma with respect thereto. Â Gemma acknowledges that Passage or Penn may bring an action with respect to any such Competitive Infringement if not requested by Gemma within such [*] period following the date of the Infringement Notice.(c)Cooperation. Â In connection with any Enforcement Action under this Section 8.6.3, Gemma shall [*]. Â Gemma shall be entitled to separate representation in an Enforcement Action by counsel of its own choice and at its own cost and expense, but Gemma shall at all times cooperate fully with Passage.8.6.4Biosimilar Action. Â Notwithstanding anything to the contrary in Section 8.6.1, during the Term, each Party shall [*] give written notice to the other Party of any application for [*] (each a â€œBiosimilar Actionâ€) of which it becomes aware and referencing [*]. Â Passage shall have the sole and exclusive right, but not the obligation, to prosecute and manage any litigation with respect to any Biosimilar Action at its cost and expense, and Gemma shall cooperate fully in any such action at Passageâ€™s cost and expense.8.6.5Recoveries. Â Unless otherwise agreed to by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.6.3, or Section 8.6.4 (whether by way of settlement or otherwise) shall [*] with respect to such action ([*]), and any remaining recovery amount shall [*], provided [*]. Â Unless otherwise agreed by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.6.2 shall [*].8.7Infringement of Third Party Rights.8.7.1Notice. Â Each Party shall promptly notify the other Party in writing within [*] after receiving a notice of a claim or assertion that any Licensed Product, or any Passage Technology, infringes or misappropriates any Third Partyâ€™s Patent Rights or other intellectual property rights in any country (â€œThird Party Infringement Claimâ€), which notice shall include a copy of any summons or complaint (or the equivalent thereof), including, if applicable, a certified 31â€‹â€‹translation into English, received regarding the foregoing. Â Thereafter, the Parties shall promptly meet to consider the Third Party Infringement Claim and the appropriate course of action and may, if appropriate, agree on and enter into a â€œjoint defense agreementâ€ wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Â The Parties shall assert and not waive the joint defense privilege, attorney work-product doctrine, attorney client privileges or any other privileges or protections that may apply with respect to any communications between the Parties in connection with the defense of such claim or assertion.8.7.2Defense. Â Unless the alleged infringing Party seeks indemnification for a Third Party Infringement Claim pursuant to Section 10.1 or Section 10.2, as between the Parties, the alleged infringing Party [*]. Â Neither Party shall enter into any settlement of any such Third Party claim that materially adversely affects the other Partyâ€™s rights or interests under this Agreement or imposes any obligation or liability on the other Party without the other Partyâ€™s prior written consent (or with respect to Gemma, that materially adversely affects Pennâ€™s rights or interests in the Licensed UPenn Patents or imposes any obligation or liability on Penn without Passageâ€™s prior written consent).8.8Patent Marking. Â Gemma shall mark all Licensed Products in accordance with applicable patent marking laws and shall require all of its Affiliates and Sublicensees to do the same.8.9Trademarks. Â Gemma will solely own all right, title and interest in and to any trademarks adopted for use with the Licensed Products for the Indication in the Field of Use in the Territory, and will be responsible for the registration, filing, maintenance and enforcement thereof. Â Neither Passage nor any of its Affiliates will at any time do or authorize to be done any act or thing which is likely to materially impair the rights of Gemma therein, and will not at any time claim any right of interest in or to such marks or the registrations or applications therefor. Â Neither Passage nor any of its Affiliates will use Gemmaâ€™s or any of its Affiliatesâ€™ trademarks or any trademark that is confusingly similar thereto.Article 9â€‹REPRESENTATIONS, WARRANTIES, AND COVENANTS9.1Representations and Warranties of Each Party. Â Each Party represents and warrants to the other as of the Effective Date that:9.1.1such Party is duly organized and validly

existing under the Laws of the jurisdiction of its incorporation or organization;9.1.2such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;9.1.3this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditorsâ€™ rights generally and by general equitable principles; and32â€‹â€‹9.1.4such Party has all right, power and authority to enter into this Agreement and to perform its obligations under this Agreement.9.2Representations and Warranties of Passage. Â Passage represents and warrants to Gemma as of the Effective Date that:9.2.1it Controls all of the UPenn Patents;9.2.2it has received no written notice or allegation, and has no other reasonable basis to believe, that any of the Licensed UPenn Patents are invalid or unenforceable, or that the use, development, practicing or exploitation of any Licensed UPenn Patents infringes the Patent Rights of any Third Party (provided, for clarity, that this Section 9.2.2 will not be construed as requiring Passage to discover, or to conduct any investigation regarding, the Patent Rights of any Third Party of which Passage has no actual knowledge and with respect to which it has not received any written notice or allegation);9.2.3it has not granted any license or option rights nor made any contractual commitments that are inconsistent with the rights granted to Gemma hereunder;9.2.4to the knowledge of Passage, the License includes all available Patent Rights Controlled by Passage that are necessary for the Development, Manufacture and Commercialization of the Licensed Products for the Indication in the Field of Use in the Territory.9.3Mutual Covenants. Â Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, such Party shall, and shall cause its Affiliates, Sublicensees and subcontractors to, comply with Law, including, as applicable, cGMP, cGLP and cGCP. Â Without limiting the foregoing, the Parties additionally agree as follows:9.3.1Data Privacy. Â Each Party shall: (a) comply with Law in relation to data protection, privacy, or restrictions on, or requirements in respect of, the processing of Personal Data of any kind, including the Health Insurance Portability and Accountability Act, General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR), and any equivalent Law in any other jurisdiction (as any of the foregoing may be amended from time to time, collectively, â€œData Protection Lawsâ€) with respect to the collection, use, transfer, storage, destruction, aggregation or other use of subject health information or other Personal Data (as defined in the applicable Data Protection Laws, collectively, â€œPersonal Dataâ€) in connection with its activities under or in connection with this Agreement, including the Development and Commercialization of any Licensed Product hereunder; (b) implement appropriate and reasonable security processes and controls in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of Personal Data in accordance with Data Protection Laws; and (c) take such steps as necessary to comply with Data Protection Laws to permit such Party to disclose Personal Data to the other Party and to permit the other Party to use and disclose such Personal Data for its own purposes in accordance with this Agreement. Â Without limiting the foregoing, if required by Law, the Parties will negotiate and enter into a written agreement with respect to the collection, storage, transfer, processing and use of Personal Data by the Parties and their Affiliates as contemplated by this Agreement.33â€‹â€‹9.3.2No Debarment or Regulatory Sanction. Â Neither Party shall employ (or, knowingly use any contractor, subcontractor, distributor or other Person that provides services to such Party in connection with this Agreement that employs) any Person that is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority (including, as applicable, the FDA pursuant to its authority under Sections 306(a)Â andÂ (b) of the FD&C Act) or that is the subject of any investigation or proceeding which may result in debarment, disqualification, blacklisting, banning or any similar sanction by any applicable Regulatory Authority, in each case, in connection with the performance of its activities under this Agreement. Â Each Party shall notify the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority or becomes the subject of any such investigation or proceeding.9.4Passage Covenants. Â Passage hereby covenants to Gemma during the Term that (a) it shall, and shall cause its Affiliates to, remain in compliance in all material respects with the UPenn Agreement, and it shall promptly provide to Gemma any written notice received from or provided to the counterparty to the UPenn Agreement that relates to Gemmaâ€™s rights or obligations hereunder, including any notice of breach or default, and (b) it will not (and will cause its Affiliates not to), without Gemmaâ€™s prior written consent, grant to any Third Party any license or other right, or any lien or security interest, with respect to any of the Passage Technology in a manner that would conflict with or impair any of the rights or licenses granted to Gemma hereunder.9.5Gemma Covenants. Â Gemma hereby covenants to Passage that it shall, and shall cause its Affiliates, Sublicensees and subcontractors to (a) not directly or indirectly (including where the same is done by a Third Party on behalf of Gemma or its Affiliates, at the urging of Gemma or its Affiliates or with the assistance of Gemma or its Affiliates) institute or make any Challenge of any Licensed UPenn Patents; provided, however, that if any Licensed UPenn Patent is asserted against Gemma or its Affiliates for activities authorized under this Agreement, then Gemma or its Affiliates (or the Sublicensee or sub-Sublicensee) is entitled to all and any defenses available to it including challenging the validity or enforceability of such Patent Right; (b) comply with all Laws that apply to its activities or obligations under this Agreement (e.g., Gemma will comply with applicable United States export laws and regulations) and Gemma acknowledges and agrees the transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Gemma that Gemma will not export data or commodities to certain foreign countries without the prior approval of the agency; and (c) not grant a security interest in any Licensed UPenn Patents.9.6No Other Warranties.9.6.1EXCEPT AS EXPRESSLY SET FORTH HEREIN, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF PASSAGE, GEMMA, OR THEIR RESPECTIVE AFFILIATES; AND (B) ALL OTHER WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY DISCLAIMED BY THE PARTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. Â PASSAGE MAKES NO WARRANTY, EITHER EXPRESS OR IMPLIED, THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF 34â€‹â€‹THE LICENSED COMPOUND OR LICENSED PRODUCTS WILL BE SUCCESSFUL OR ACHIEVE ANY PARTICULAR RESULT.9.6.2Furthermore, nothing in this Agreement will be construed as:(a)A representation or warranty by Passage as to the validity or scope of any Licensed UPenn Patents;(b)A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;(c)Obligating Passage to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement; and(d)Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Passage other than the Licensed UPenn Patents as defined herein, regardless of whether such Patent Rights are dominant or subordinate to the Licensed UPenn Patents.9.6.3Gemma acknowledges and agrees that it has conducted diligence relating to the Passage Technology, and has been offered the opportunity to ask representatives of Passage questions about the Passage Technology. Â Passage represents that it has provided such available information as Licensee has requested relating to such Passage Technology and any additional available information that Passage knows to be material to the diligence conducted by Gemma.Article 10â€‹INDEMNIFICATION10.1Indemnification by Gemma.10.1.1Indemnification of Passage. Â Gemma shall defend, indemnify and hold Passage, its Affiliates and their respective directors, officers, employees, contractors and agents (the â€œPassage Indemniteesâ€) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneysâ€™ fees), including, bodily injury, risk of bodily injury, death and property damage (collectively, â€œLossesâ€) arising out of Third Party claims or suits (each, a â€œThird Party Claimâ€) related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; (b) any breach of this Agreement by Gemma; or (c) the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Gemma or its Affiliates or Sublicensees; except, in each case (a)-(c), to the extent such Losses arise out of any conditions set forth in Sections 10.2(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 10.2.35â€‹â€‹10.1.2Indemnification of Passage under the UPenn Agreement. Â Without limiting Section 10.1.1, Gemma shall defend, indemnify and hold the Passage Indemnitees harmless from and against any and all Losses related to either (or both) of the UPenn Letter Agreements or a breach of the UPenn Agreement by Passage, in each case, caused by any acts or omissions of a Gemma Indemnitee; except to the extent such Losses arise out of any conditions set forth in Sections 10.2(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 10.2.10.1.3Indemnification of Penn. Â Gemma shall defend, indemnify and hold Penn and its respective trustees, officers, faculty, students, employees, contractors and agents (the â€œPenn Indemniteesâ€) harmless from and against any and all Losses arising out of a Third Party Claim related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; (b) any breach of this Agreement by Gemma; (c) the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Gemma or its Affiliates or Sublicensees; or (d) any enforcement action or suit brought by Gemma against a Third Party for infringement of any UPenn Patent; provided that Gemmaâ€™s obligations pursuant to this Section 10.1.3 shall not apply to the extent such claims or suits result from the gross negligence or willful misconduct of any of Penn Indemnitees as determined by a court of law.10.2Indemnification by Passage. Â Passage shall defend, indemnify and hold Gemma, its Affiliates and their respective directors, officers, employees, contractors and agents (the â€œGemma Indemniteesâ€) harmless from and against any and all Losses arising out of any Third Party Claim related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Passage, its Affiliates and its or their respective directors, officers, employees and agents, in connection with Passageâ€™s performance of its obligations or exercise of its rights under this Agreement; or (b) any breach of this Agreement by Passage; except, in each case (a)-(b), to the extent such Losses arise out of any conditions set forth in Sections 10.1(a)-(c) for which Gemma is obligated to indemnify any Passage Indemnitee under Section 10.1.10.3Procedure.10.3.1Notice. Â The Party seeking indemnification under Section 10.1 or Section 10.2 (the â€œIndemnified Partyâ€) shall inform the other Party (the â€œIndemnifying Partyâ€) of the Third Party Claim giving rise to the obligation to indemnify pursuant to such Section within [*] after receiving written notice of such Third Party Claim, it being understood and agreed, however, that the failure or delay by an Indemnified Party to timely give such notice shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party is actually and materially prejudiced as a result of such failure or delay to give notice.10.3.2Procedure. Â The Indemnifying Party shall assume and conduct the defense of the Third Party Claim using counsel of its choice; provided, however, that the Indemnified Party may participate in and monitor such defense with counsel of its choice at its own expense, subject to the Indemnifying Partyâ€™s right to control such defense. Â With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense: (a) the Indemnified Party shall provide 36â€‹â€‹the Indemnifying Party with reasonable assistance, at the Indemnifying Partyâ€™s expense, in connection with such defense, (b) the Indemnifying Party shall not settle any Third Party Claim without the prior written consent of the Indemnified Party if the settlement would: (i) result in or impose any obligation (including any payment obligation) on the Indemnified Party, or (ii) result in any admission of wrong-doing or fault by the Indemnified Party, and (c) so long as the Indemnifying Party is actively defending the Third Party Claim in good faith, the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party. Â If the Parties cannot agree as to the application of Section 10.1 or Section 10.2 to any Third Party Claim, pending resolution of the dispute pursuant to Section 12.6, the Parties may conduct separate defenses of such Third Party Claim(s), with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or Section 10.2, as applicable, upon resolution of the underlying claim. Â If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, (A) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate, and (B) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided under Section 10.1 or Section 10.2. Â Notwithstanding anything to the contrary in this Section 10.3.2, in the event that Passage or Penn believes in good faith that a bona fide conflict exists between Gemma and Passage or Penn or any other Passage Indemnitee or Penn Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Passage or Penn or any other Passage Indemnitee or Penn Indemnitee shall have the right to defend against any such claim or suit itself, including by selecting its own counsel, with any reasonable attorneyâ€™s fees and litigation expenses being paid for by Gemma. Â Gemma will pay such fees and expenses either directly or will reimburse such Person within [*] after Gemmaâ€™s receipt of an invoice for such fees and expenses.10.4Insurance. Â Within [*] of the Effective Date, Gemma shall (and shall cause its Affiliates to) obtain commercial general liability, product liability and other appropriate insurance in an amount consistent with industry standards in light of its obligations under this Agreement, including:10.4.1Commercial Form General Liability Insurance (contractual liability included) with limits no less than as follows:(a)Each occurrence [*];(b)General aggregate [*]; and10.4.2Prior to the commencement of Clinical Studies: (a)Clinical trials liability insurance with limits no less than [*]; and10.4.3Prior to the First Commercial Sale:(a)Products liability insurance with limits no less than[*].Gemma shall (and shall cause its Affiliates and Sublicensees to) maintain such insurance (including in the amounts set forth above) during the Term and for [*] thereafter. Â Passage may 37â€‹â€‹review periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section, and has the right to require Gemma to adjust the limits in Passageâ€™s reasonable discretion.10.4.4Gemma expressly understands, however, that the coverages and limits in this Section 10.4 do not in any way limit Gemmaâ€™s liability or indemnification obligations. Â Gemmaâ€™s insurance will:(a)Be issued by an insurance carrier with an [*] or better;(b)Provide for [*] advance written notice to Passage and Penn of any modification;(c)State that Passage and Penn are endorsed as an additional insured with respect to the coverages in this Section 10.4; and(d)Include a provision that the coverages will be primary and will not participate with nor will be excess over any valid and collective insurance or program of self-insurance carried or maintained by Passage or Penn.10.4.5Gemma shall furnish to Passage (and if requested by Passage, Penn) (a) a valid certificate of insurance evidencing compliance with all requirements of this Agreement, and (b) additional insured endorsements for Gemmaâ€™s applicable policies naming Passage and â€œThe Trustees of the University of Pennsylvaniaâ€ as additional insureds. Â Gemma shall furnish both documents within [*] after the Effective Date, once per year thereafter, and at any time there is a modification in or to such insurance.10.5Limitation of Liability. Â EACH PARTY AND ITS AFFILIATES SHALL NOT BE LIABLE TO THE OTHER PARTY AND ITS AFFILIATES FOR (A) ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES, OR (B) ANY LOSS OF PROFITS OR REVENUE, IN EACH CASE (A) AND (B) ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF WHETHER SUCH CLAIM IS IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. Â NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (I) A PARTYâ€™S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.1 OR SECTION 10.2, OR (II) LIABILITIES ARISING FROM A PARTYâ€™S BREACH OF ITS OBLIGATIONS UNDER SECTION 3.1 OR ARTICLEÂ 7.Article 11â€‹TERM AND TERMINATION11.1Term. Â This Agreement shall be effective commencing on the Effective Date and shall expire in its entirety upon the expiration of the last to expire Royalty Term with respect to all Licensed Products and all countries (the â€œTermâ€), unless terminated earlier in accordance with this Article 11 or by mutual written agreement of the Parties. Â Following the expiration of the Royalty Term for a Licensed Product in a particular country, the License shall become non-exclusive, fully paid-up and royalty-free (subject to any payments owed under the UPenn 38â€‹â€‹Agreement in and for such country), perpetual, and irrevocable for such Licensed Product in and for such country. Â Upon the expiration of the Term, the License shall become non-exclusive, fully paid-up and royalty-free (subject to any payments owed under the UPenn Agreement), perpetual, and irrevocable in its entirety.11.2Termination for Diligence Event Failure. In the event Gemma fails to achieve any Diligence Event by the corresponding Achievement Date (as the same may be extended under this Agreement in accordance with Section 6.7) and does not cure such breach within [*] after Gemmaâ€™s receipt of written notice (or a longer period of up to [*] if the Parties mutually agree that such longer period is necessary and acceptable) to the reasonable satisfaction of Passage or Penn, as applicable, Passage shall have the right and option to terminate this Agreement, upon written notice, with immediate effect.11.3Termination for Convenience; Termination for Cause.11.3.1Gemma may, at its convenience, terminate this Agreement in its entirety or terminate a Licensed Product for the Indication in the Field of Use, upon providing at least [*] prior written notice to Passage of such intention to terminate, provided that upon termination of a Licensed Product, except as set forth in Section 11.7.3, Gemma shall cease using the License for making, using, or selling the affected Licensed Product for the Indication in the Field of Use; provided further, that Gemma may not terminate this Agreement in its entirety or terminate a Licensed Product for the Indication in the Field of Use, in either case for convenience prior to the first anniversary of the Effective Date and the full payment of the amounts due to Passage under Section 5.1.11.3.2Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and does not cure such breach within [*] (or within [*] with respect to a breach of any payment obligation) following receipt of written notice of such breach from the non-breaching Party; provided however, that if the breach is capable of being cured, but cure of such breach

cannot reasonably be effected within such [*] period, then the cure period shall be extended an additional [*] (for a total of [*] following receipt of written notice of such breach from the non-breaching Party). Â Additionally, Passage shall have the right to terminate this Agreement in its entirety (i) upon [*] written notice if Gemma fails to comply with any Laws that apply to its activities or obligations under this Agreement, which failure(s) can be remedied, and Gemma fails to remedy such lack of compliance within such [*] period, and (ii) upon written notice, with immediate effect, if Gemma grants a security interest in any Licensed UPenn Patents.11.4Termination for Bankruptcy.11.4.1Right to Terminate. Â Each Party shall have the right to terminate this Agreement effective immediately upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [*] of its filing, 39â€‹â€‹or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.11.4.2Rights in Bankruptcy. Â All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of SectionÂ 365(n) of Title 11 of the United States Code (â€œUS Bankruptcy Codeâ€) or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to â€œintellectual propertyâ€ as defined under SectionÂ 101 of the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. Â In the event that a case under the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws is commenced by or against a Party, the other Party shall have all of the rights and elections set forth in Section 365(n) or comparable provision of applicable bankruptcy or insolvency laws to the maximum extent permitted thereby. Â The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the US Bankruptcy Code or any comparable provision of applicable bankruptcy or insolvency laws, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in such other Partyâ€™s possession, shall be promptly delivered to such other Party (i) upon any such commencement of a bankruptcy proceeding upon such other Partyâ€™s written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i), following the rejection of this Agreement by such Party upon written request therefor by such other Party. Â The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws: (a) the right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development, Manufacture or Commercialization of the Licensed Products; (b) the right to contract directly with any Third Party described in (a) to complete the contracted work; and (c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.11.5Termination for Patent Challenge. Â In the event that Gemma or any of its Affiliates or Sublicensees directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any Licensed UPenn Patent as being invalid, unenforceable or otherwise not patentable, this Agreement shall immediately and automatically terminate in its entirety upon the initiation of such challenge, with or without any further action by Passage; provided, however, that this Agreement shall not so automatically terminate if Gemma (or its Affiliate) or such Sublicensee challenged such Licensed UPenn Patent in defense of claims asserted by or on behalf of Passage (or its Affiliate) against Gemma (or its Affiliate) or such Sublicensee, for activities authorized under this Agreement pursuant to Section 9.5(a).11.6Full Force and Effect During Notice Period. Â This Agreement shall remain in full force and effect during the period commencing on the date of notice of termination of this Agreement and ending on the effective date of termination of this Agreement, including that Gemma shall owe royalties on Net Sales of Licensed Products made during such period, and shall be obligated to make any Development Milestone Payment or Sales Milestone Payment achieved 40â€‹â€‹during such period, even if the due date of such payment comes after the effective date of termination.11.7Effect of Termination. Â Without limiting any other legal or equitable remedies that either Party may have under this Agreement, in the event of termination of this Agreement in its entirety for any reason, the terms of this Section 11.7 will apply as of the effective date of such termination.11.7.1Licenses. Â All rights and licenses granted by either Party to the other Party pursuant to this Agreement shall terminate, and, subject to Section 11.7.2, all sublicenses granted hereunder by Gemma or its Affiliates shall also terminate.11.7.2Sublicense Survival. Â Upon termination of this Agreement for any reason (other than any such termination that results in the termination of the UPenn Agreement with respect to the Indication), upon the request of any Third Party Sublicensee, Passage will enter into a direct license with such Sublicensee on the same terms as this Agreement, taking into account any differences in license scope, territory and duration of the sublicense grant and, subject to the proviso in this sentence, Passage will, and does hereby grant to each such Sublicensee, a direct license during the period from the termination of this Agreement until Passage and each such Sublicensee have entered into such direct license (each a â€œNew License Agreementâ€); provided that, at the time of such termination, (a) such Sublicensee is not in breach of its sublicense agreement with Gemma or its Affiliate, and (b) the UPenn Agreement remains in full effect with respect to the Indication. Â Under any such New License Agreement between Passage and such former Sublicensee, such former Sublicensee will be required to pay to Passage the same amounts in consideration for such direct license as Passage would have received from Gemma pursuant to this Agreement on account of such former Sublicenseeâ€™s Development or Commercialization of Licensed Products had this Agreement not been terminated. Â Under such New License Agreement, Passage will not be bound by any grant of rights broader than, and will not be required to perform any obligations other than those rights and obligations contained in this Agreement, and all applicable rights of Passage set forth in this Agreement will be included in such New License Agreement. Â Notwithstanding the foregoing, Passage will not be obligated to enter into a New License Agreement with a Third Party Sublicensee of Gemma unless such Sublicensee notifies Passage within [*] after the termination of this Agreement that it wishes to enter into a New License Agreement.11.7.3Winddown; Sell-Off. Â Gemma shall be responsible for the prompt wind-down of Gemmaâ€™s, its Affiliatesâ€™ and their respective Sublicenseesâ€™ Development, Manufacturing and Commercialization of the Licensed Products in the Territory in compliance with Law. Â Notwithstanding the foregoing, other than in the event of termination of this Agreement by Passage pursuant to Section 11.2, Section 11.3(b), or Section 11.4, and so long as the UPenn Agreement is still in effect with respect to the Licensed Products, during the [*] period following the effective date of termination, Gemma and its Affiliates and Sublicensees shall have the right to sell or otherwise dispose of all Licensed Products for the Indication then in its or their respective inventory and any in-progress inventory; provided that Gemma shall continue to make payments to Passage on Net Sales of such Licensed Products in accordance with SectionÂ 5.4, and the rights and licenses granted to Gemma hereunder shall survive to the extent necessary for Gemma (and its Affiliates and Sublicensees) to conduct such sell-off. Â Except in connection with activities 41â€‹â€‹pursuant to the foregoing, Gemma, its Affiliates and, subject to Section 11.7.2, Sublicensees shall cease all exploitation of the Licensed Products.11.8Program Reversion. Â Passage shall have, and Gemma hereby grants to Passage, effective upon termination of this Agreement for any reason other than in the event of termination of this Agreement by Gemma pursuant to [*], a worldwide, fully-paid, royalty-free, perpetual, irrevocable, sublicensable (through multiple tiers) exclusive license under any Gemma Collaboration Know-How and Gemma Collaboration Patents solely to Develop, Manufacture, and Commercialize the Licensed Products in the Indication in the Field of Use in the Territory. Â In addition, upon Passageâ€™s request in writing within [*] after the effective date of termination, subject to Section 11.7.2, Gemma shall (and shall cause its Affiliates and Sublicensees to) (i) transfer and assign to Passage or its designee all Regulatory Submissions and Regulatory Approvals Controlled by Gemma, its Affiliates or Sublicensees for the Licensed Products in the Indication in the Field of Use, and (ii) transfer, or at Passageâ€™s election, wind-down the conduct of any ongoing Clinical Studies for a Licensed Product in the Indication in the Field of Use then being conducted by Gemma, its Affiliates or Sublicensees to Passage or its designee, or (iii) subject to Section 11.7.3, transfer to Passage all inventory of Licensed Products in the Indication then Controlled by Gemma, its Affiliates or Sublicensees at the actual cost of such supply, plus any reasonable costs associated with such transfer; provided that other than in the event of termination of this Agreement pursuant to Section 11.3(b) by Gemma, all such transfers (or wind-downs) shall be at Gemmaâ€™s sole cost and expense.11.9Confidential Information. Â Upon the expiration or termination of this Agreement in its entirety, at the disclosing Partyâ€™s election, the receiving Party shall return or destroy all tangible materials to the extent comprising, bearing or containing any Confidential Information of the disclosing Party that are in the receiving Partyâ€™s or its Affiliatesâ€™ respective possession or control and provide written certification of such destruction (if applicable) to the disclosing Party; provided that the receiving Party may retain one (1) copy of such Confidential Information for its archives solely to monitor compliance with its obligations herein or may retain such Confidential Information for which it has any continuing rights; and provided further that the receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures.11.10Termination Not Sole Remedy. Â Termination is neither Partyâ€™s sole remedy under this Agreement and, whether or not termination is effected by a Party and notwithstanding anything contained in this Agreement to the contrary, all other remedies in law or equity shall remain available to both Parties except as agreed to otherwise herein.11.11Survival. Â Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Â In addition, the following provisions of this Agreement shall survive expiration or termination of this Agreement: Article 1, Article 7, Article 8, Article 10, Article 11, Article 12, and Sections 2.6, 5.10, and 9.6.Article 12â€‹MISCELLANEOUS42â€‹â€‹12.1Assignment.12.1.1Generally. Â This Agreement may not be assigned or transferred by either Party in whole or in part without the prior written consent of the other Party. Â Notwithstanding the foregoing, either Party shall have the right, without the prior written consent of the other Party, to assign or transfer this Agreement or its rights and obligations hereunder to (i) its Affiliate, or (ii) its successor in interest in connection with a Change of Control. Â A Party shall notify the other Party in writing of any assignment of this Agreement by such Party within [*] thereof. Â The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the applicable Party. Â Any attempted assignment not in accordance with this Section 12.1 shall be void. Â Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.12.1.2Effect of Change of Control.(a)Whether or not this Agreement is assigned by Passage pursuant to Section 12.1.1, the Parties agree that all Patent Rights, Know-How, Regulatory Materials, Materials or other intellectual property rights of any Acquiror of Passage will be deemed not to be â€œControlledâ€ by Passage for purposes of this Agreement and will be automatically excluded from the rights licensed to Gemma under this Agreement.(b)Notwithstanding anything in Section 5.1 to the contrary, any unpaid portion of the amounts due to Passage under Section 5.1 shall become immediately due and payable to Passage upon a Change of Control.12.2Use of Affiliates. Â Either Party shall have the right to exercise its rights and perform its obligations under this Agreement through any of its Affiliates. Â In each case where a Partyâ€™s Affiliate has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement, (a) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement, and (b) any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions.12.3No Discrimination. Â Neither Party will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.12.4Severability. Â Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.12.5Governing Law; English Language. Â This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, without reference to any rules of conflict of laws that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Â The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable. Â 43â€‹â€‹This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.12.6Dispute Resolution.12.6.1Disputes. Â Any dispute, controversy or claim arising from or related to this Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination hereof (a â€œDisputeâ€) that is not an Excluded Claim (as defined below) shall be finally resolved in accordance with Section 12.6.2. Â Notwithstanding the foregoing, any decisions that are subject to mutual agreement of the Parties will not be subject to the provisions of this Section 12.6 so long as such decisions are made in accordance with this Agreement.12.6.2Early Resolution; Arbitration.(a)Early Resolution. Â Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Â Any final decision mutually agreed to by the Executive Officers shall be set forth in writing and shall be conclusive and binding on the Parties. Â If the Executive Officers are not able to agree on the resolution of any such Dispute within [*] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then the Parties shall submit such Dispute to be finally resolved by arbitration in accordance with Section 12.6.2(b). Â To the extent any Dispute relates to an action or decision required to be taken or made under the UPenn Agreement within a certain time period, the Parties shall use their best efforts to resolve such Dispute within such time period required for such action or decision. To the extent any such Dispute has not been resolved with such time period, and notwithstanding anything herein to the contrary, Passage shall have final decision making authority with respect to, and nothing herein shall prevent Passage from taking or making, any such action or decision required to be taken or made under the UPenn Agreement within such time period.(b)Arbitration. Â Any arbitration will be administered by the American Arbitration Association (â€œAAAâ€) in accordance with the AAAâ€™s Commercial Arbitration Rules in effect at the time of submission, as modified by this Section 12.6.2(b). Â The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the biopharmaceutical industry, each of whom will be impartial and independent. Â Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [*] following appointment of the second arbitrator, by the AAA. Â Such arbitration will take place in Philadelphia, Pennsylvania and will be conducted in English. Â The arbitration award will be a final and binding determination of the Dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 10.5. Â Subject to any award by the arbitration panel, each Party shall be responsible for its fees, costs, and expenses for conducting the arbitration; provided that the Parties will share payment for the third arbitrator.12.6.3Confidentiality. Â Except to the extent necessary to comply with Law, legal process or a court order, or to enforce a final settlement agreement or secure enforcement of any arbitration award, the Parties agree that the existence, terms and content of any arbitration pursuant 44â€‹â€‹to Section 12.6.2(b), all information and documents disclosed in any such arbitration or evidencing any such arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any such arbitration, shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.12.6.4Excluded Claims. Â As used in this Section 12.6, the term â€œExcluded Claimâ€ means a dispute, controversy or claim that concerns (a) the validity or infringement of a Patent Right, trademark, copyright, or trade secret, or (b) any antitrust-, anti-monopoly- or competition-related Law. Â Any action concerning Excluded Claims may be brought in any court having jurisdiction.12.6.5Equitable Relief. Â Nothing in this Section 12.6 shall preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief, either prior to or during any arbitration, to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.12.7Waivers and Amendments. Â The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Â Any waivers under this Agreement must be in writing to be effective. Â No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.12.8Relationship of the Parties. Â The Parties have the relationship of independent contractors to each other under this Agreement, and nothing contained herein is intended or is to be construed so as to constitute one Party as a partner, agent, or joint venturer of the other Party. Â In addition, nothing in this Agreement shall be construed to give a Party the power or authority to act for, bind or commit the other Party or its Affiliates to or under any contract, agreement, or undertaking with any Third Party.12.9Notices. Â All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file) and sent as an attachment to an e-mail message, or (b) the earlier of when received by the addressee or [*] after the date it was sent, if sent by registered mail or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses or e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):If to Passage: Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: Chief Executive Officerâ€‹45â€‹â€‹With a copy to (which shall not

constitute notice):Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: General Counselâ€‹If to Gemma:Gemma Biotherapeutics, Inc.1831 Delancey PlacePhiladelphia, PA 19103ATTN: Chief Executive Officerâ€‹With a copy to (which shall not constitute notice): McDermott Will & Emery LLP200 Clarendon Street, Floor 58Boston, MA 02116ATTN: Brian Bunnâ€‹â€‹12.10No Third Party Beneficiary Rights. Â This Agreement is not intended to and shall 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 this Agreement or any provision contained herein or contemplated hereby. Â Notwithstanding the foregoing, each of Passage and Gemma agree and acknowledge that Penn is an intended third party beneficiary, and is entitled to rely on, the representations, warranties and covenants of Gemma, and remedies, set forth herein as if an original party to this Agreement.12.11Further Assurances. Â Passage and Gemma hereby agree without the necessity of any further consideration to execute, acknowledge, and deliver any and all administrative documents and take any ministerial action as may be reasonably necessary to carry out the intent and purposes of this Agreement.12.12Entire Agreement. Â This Agreement, the UPenn Agreement, and the Transition Services Agreement, including all Exhibits and Schedules hereto and thereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter, including the CDA.12.13Counterparts. Â This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. Â All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Â Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an â€œElectronic Deliveryâ€) shall be treated in all manners and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Â Neither Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature 46â€‹â€‹or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.12.14Expenses. Â Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and signing of this Agreement.12.15Construction. Â The Parties acknowledge and agree that (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, and (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement.12.16Interpretation. Â The captions and headings in this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Â Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits of or to this Agreement and references to this Agreement include all Exhibits and Schedules hereto. Â If any conflict exists between the main body of this Agreement and any Exhibit or Schedule hereto, the main body of this Agreement shall prevail. Â Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words â€œincludeâ€ or â€œincludingâ€ shall be construed as incorporating, also, â€œbut not limited toâ€ or â€œwithout limitation;â€ (b) the word â€œdayâ€ or â€œyearâ€ means a calendar day or year unless otherwise specified; (c) the words â€œhereof,â€ â€œherein,â€ â€œherebyâ€ and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (d) the words â€œshallâ€ and â€œwillâ€ have interchangeable meanings for purposes of this Agreement; (e) the word â€œorâ€ shall have the inclusive meaning commonly associated with â€œand/orâ€; (f) words of any gender include the other genders; (g) words using the singular or plural number also include the plural or singular number, respectively; and (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.12.17Cumulative Remedies. Â No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, and each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.12.18Export. Â This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Gemma or Passage from time to time. Â Each Party agrees that it will not export, directly or indirectly, any 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 Body approval, without first obtaining the written consent to do so from the appropriate Governmental Body. [Signature page follows]â€‹47â€‹IN WITNESS WHEREOF, the Parties intending to be legally bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.â€‹Passage Bio, Inc.Gemma Biotherapeutics, Inc.â€‹â€‹By: /s/ Will Chou_____â€‹By: /s/ Annalisa Jenkins_____Name: Will Chou, M.D.â€‹Name: Annalisa JenkinsTitle: Chief Executive OfficerTitle: Presidentâ€‹â€‹List of Schedules:â€‹Schedule 1.61: Licensed CompoundSchedule 1.121: UPenn Patents (existing as of the Effective Date)â€‹List of Exhibits:â€‹Exhibit A: Specified ObligationsExhibit B: Form of SDR ReportExhibit C: Form of Financial ReportExhibit D: Third Party MilestonesExhibit E: Diligence Eventsâ€‹[Signature Page to Exclusive License Agreement (Krabbe)]â€‹â€‹SCHEDULE 1.61LICENSED COMPOUNDâ€‹[*]â€‹â€‹SCHEDULE 1.121UPENN PATENTSâ€‹[*]â€‹â€‹â€‹EXHIBIT ASPECIFIED OBLIGATIONSâ€‹[*]â€‹â€‹â€‹EXHIBIT BFORM OF SDR REPORTâ€‹[*]â€‹â€‹â€‹EXHIBIT CFORM OF FINANCIAL REPORTâ€‹[*]â€‹EXHIBIT DTHIRD PARTY MILESTONESâ€‹[*]â€‹â€‹â€‹EXHIBIT EDILIGENCE EVENTSâ€‹[*] â€œExhibit 10.3â€‹Execution VersionConfidentialâ€‹CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT PASSAGE BIO, INC. TREATS AS PRIVATE OR CONFIDENTIAL.â€‹EXCLUSIVE LICENSE AGREEMENTBy and betweenPassage Bio, Inc.andGemma Biotherapeutics, INC.July 31, 2024â€‹â€‹Execution VersionConfidentialâ€‹â€‹TABLE OF CONTENTSPageArticle 1 DEFINITIONS & INTERPRETATIONâ€Œ2Article 2 LICENSEâ€Œ152.1 Exclusive License to Gemmaâ€Œ152.2 Retained Rightsâ€Œ152.3 Right to Sublicenseâ€Œ152.4 Right to Subcontractâ€Œ162.5 Right of Access and Referenceâ€Œ172.6 No Implied Licensesâ€Œ172.7 Upstream Licenseâ€Œ172.8 Third Party Licensesâ€Œ18Article 3 EXCLUSIVITYâ€Œ193.1 Exclusivityâ€Œ183.2 Exception for Change of Controlâ€Œ18Article 4 GOVERNANCEâ€Œ194.1 Alliance Managersâ€Œ194.2 Cooperation with UPenn Agreement Committeesâ€Œ19Article 5 PAYMENTSâ€Œ195.1 Product Supply; Upfront Feeâ€Œ195.2 Development and Regulatory Milestonesâ€Œ195.3 Sales Milestonesâ€Œ205.4 Royalty Paymentsâ€Œ205.5 Payment Termsâ€Œ225.6 Payment Currency; Exchange Rate; Offsetâ€Œ225.7 Late Paymentsâ€Œ235.8 Payments to Third Partiesâ€Œ235.9 Accountingâ€Œ235.10 Records and Audit Rightsâ€Œ235.11 Taxesâ€Œ245.12 Blocked Currencyâ€Œ24Article 6 DEVELOPMENT AND COMMERCIALIZATIONâ€Œ246.1 Development Planâ€Œ246.2 Clinical Developmentâ€Œ246.3 Commercializationâ€Œ256.4 Manufacturingâ€Œ256.5 Regulatoryâ€Œ256.6 General Diligenceâ€Œ256.7 Diligence Eventsâ€Œ25iâ€‹â€‹FW DRAFT 6-12-20CONFIDENTIAL & PRIVILEGEDâ€‹6.8 Progress Reportsâ€Œ26Article 7 CONFIDENTIALITYâ€Œ267.1 Confidential Informationâ€Œ267.2 Duty of Confidence; Exceptionsâ€Œ277.3 Authorized Disclosuresâ€Œ277.4 Prior Confidentiality Agreementsâ€Œ287.5 Public Disclosures; Securities Filingsâ€Œ287.6 Use of Namesâ€Œ29Article 8 INTELLECTUAL PROPERTYâ€Œ298.1 Ownershipâ€Œ298.2 Patent Prosecution and Maintenanceâ€Œ298.3 Cooperation for Patent Extensionsâ€Œ308.4 Patent Listingsâ€Œ308.5 Common Interest Disclosuresâ€Œ308.6 Patent Enforcementâ€Œ308.7 Infringement of Third Party Rightsâ€Œ318.8 Patent Markingâ€Œ328.9 Trademarksâ€Œ32Article 9 REPRESENTATIONS, WARRANTIES, AND COVENANTSâ€Œ329.1 Representations and Warranties of Each Partyâ€Œ329.2 Representations and Warranties of Passageâ€Œ339.3 Mutual Covenantsâ€Œ339.4 Passage Covenantsâ€Œ349.5 Gemma Covenantsâ€Œ349.6 No Other Warrantiesâ€Œ34Article 10 INDEMNIFICATIONâ€Œ3510.1 Indemnification by Gemmaâ€Œ3510.2 Indemnification by Passageâ€Œ3610.3 Procedureâ€Œ3610.4 Insuranceâ€Œ3710.5 Limitation of Liabilityâ€Œ38Article 11 TERM AND TERMINATIONâ€Œ3811.1 Termâ€Œ3811.2 Termination for Diligence Event Failureâ€Œ3911.3 Termination for Convenience; Termination for Causeâ€Œ3911.4 Termination for Bankruptcyâ€Œ3911.5 Termination for Patent Challengeâ€Œ4011.6 Full Force and Effect During Notice Periodâ€Œ4011.7 Effect of Terminationâ€Œ4111.8 Program Reversionâ€Œ42iiâ€‹â€‹FW DRAFT 6-12-20CONFIDENTIAL & PRIVILEGEDâ€‹11.9 Confidential Informationâ€Œ4211.10 Termination Not Sole Remedyâ€Œ4211.11 Survivalâ€Œ42Article 12 MISCELLANEOUSâ€Œ4312.1 Assignmentâ€Œ4312.2 Use of Affiliatesâ€Œ4312.3 No Discriminationâ€Œ4312.4 Severabilityâ€Œ4312.5 Governing Law; English Languageâ€Œ4312.6 Dispute Resolutionâ€Œ4412.7 Waivers and Amendmentsâ€Œ4512.8 Relationship of the Partiesâ€Œ4512.9 Noticesâ€Œ4512.10 No Third Party Beneficiary Rightsâ€Œ4612.11 Further Assurancesâ€Œ4612.12 Entire Agreementâ€Œ4612.13 Counterpartsâ€Œ4612.14 Expensesâ€Œ4712.15 Constructionâ€Œ4712.16 Interpretationâ€Œ4712.17 Cumulative Remediesâ€Œ4712.18 Exportâ€Œ47â€‹â€‹iiiConfidentialEXCLUSIVE LICENSE AGREEMENTThis Exclusive License Agreement (this â€œAgreementâ€) is entered into as of July 31, 2024 (the â€œEffective Dateâ€), by and between Passage Bio, Inc., a corporation organized under the laws of Delaware (â€œPassageâ€), with offices at 2005 Market St., 39th Floor, Philadelphia, PA 19103, and Gemma Biotherapeutics, Inc., a Delaware corporation (â€œGemmaâ€), with offices at 1831 Delancey Place, Philadelphia, PA 19103. Â Passage and Gemma may be referred to in this Agreement individually as a â€œPartyâ€ or collectively as the â€œParties.â€BACKGROUNDWHEREAS, Passage is a biopharmaceutical company with expertise in the development, manufacture and commercialization of human therapeutic products for the treatment of genetic disorders;WHEREAS, concurrently with the execution of this Agreement, Passage and The Trustees of the University of Pennsylvania (â€œPennâ€) are also entering into that certain Second Amended and Restated Research, Collaboration & License Agreement, effective as of September 18, 2018, and amended and restated as of the Effective Date (as amended and restated, the â€œUPenn Agreementâ€);WHEREAS, concurrently with the execution of this Agreement, Passage and Gemma are also entering into (a) that certain Exclusive License Agreement, pursuant to which Passage will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for Krabbe disease (globoid cell leukodystrophy) (the â€œKrabbe License Agreementâ€), and (b) that certain Exclusive License Agreement, pursuant to which Passage will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for GLB1 Deficiency, for GM1 gangliosidosis-1 and MPS IV;WHEREAS, the programs contemplated by this Agreement are of mutual interest to Passage and Gemma, and may benefit Passage and Gemma through the creation or discovery of new inventions and the development and commercialization of Licensed Products (as defined herein) for the Indication (as defined herein);WHEREAS, Gemma wishes to obtain from Passage worldwide, exclusive and non-exclusive licenses to rights granted to Passage under the UPenn Agreement and certain other intellectual property rights owned or controlled by Passage, to develop, manufacture and commercialize Licensed Products for the Indication, and Passage is willing to grant such licenses to Gemma in accordance with the terms and conditions set forth herein; andWHEREAS, concurrently with the execution of this Agreement, Passage and Gemma are also entering into the Transition Services Agreement (as defined herein);NOW THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:â€‹â€‹Article 1â€‹DEFINITIONS & INTERPRETATIONWhenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 and elsewhere in this Agreement, whether used in the singular or plural, shall have the meanings specified.1.1â€œAAAâ€ has the meaning set forth in SectionÂ 12.6.2(b).1.2â€œAcquirorâ€ means a Third Party that acquires a Party through a Change of Control, together with any Affiliates of such Third Party existing immediately prior to the consummation of the Acquisition. Â For clarity, an â€œAcquirorâ€ of a Party shall exclude the Party and all of its Affiliates existing immediately prior to the consummation of the Acquisition.1.3â€œAffiliateâ€ means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. Â For the purposes of this SectionÂ 1.3, the word â€œcontrolâ€ (including, with correlative meaning, the terms â€œcontrolled byâ€ or â€œunder common control withâ€) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such Person, by contract or otherwise.1.4â€œAlliance Managerâ€ has the meaning set forth in Section 4.1.1.5â€œArising Know-Howâ€ means any and all Know-How, whether or not patentable, generated, created, developed, conceived, reduced to practice, or otherwise made during the Term by or on behalf of Gemma, its Affiliates or Sublicensees in the performance of activities under this Agreement.1.6â€œAuditing Partyâ€ has the meaning set forth in Section 5.10.2.1.7â€œBiosimilar Actionâ€ has the meaning set forth in Section 8.6.4.1.8â€œBLAâ€ means (a) a biologics license application as that term is used and defined in the PHS Act and the regulations promulgated thereunder, (b) a marketing authorization application in the European Union, or (c) any equivalent or comparable application, registration or certification in any other country or region.1.9â€œBusiness Dayâ€ means a day other than a Saturday, Sunday, or other day on which banking institutions in Philadelphia, PA, USA are authorized or required by Law to remain closed.1.10â€œCalendar Quarterâ€ mean the respective periods of three (3) consecutive calendar months ending on MarchÂ 31, JuneÂ 30, SeptemberÂ 30, and DecemberÂ 31 of each Calendar Year.1.11â€œCalendar Yearâ€ means each successive period of twelve (12) months commencing on JanuaryÂ 1 and ending on DecemberÂ 31.1.12â€œCDAâ€ has the meaning set forth in Section 7.4.2â€‹â€‹1.13â€œcGCPâ€ means the applicable then-current standards for clinical activities for pharmaceuticals or biologicals, as set forth in the FD&C Act and any regulations or guidance documents promulgated thereunder, as amended from time to time, together with, with respect to work performed in a country other than the United States, any similar standards of good clinical practice as are required by any Regulatory Authority in such country.1.14â€œcGLPâ€ means the current good laboratory practice regulations promulgated by the FDA, published at 21 US C.F.R. Â§Â 58, and equivalent non-United States regulations and standards in or for the Territory, as applicable, as such current laboratory practices, regulations and standards may be amended from time to time.1.15â€œcGMPâ€ means those current practices, as amended from time to time, related to the manufacture of pharmaceutical or biological products and any precursors thereto promulgated in guidelines and regulations of standard compilations, including the cGMP Rules of the World Health Organization, the United States Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (established by the United States Department of Health and Human Services), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical or biological products, and equivalent guidelines, regulations and standards in or for the Territory, as such guidelines, regulations and standards may be amended from time to time.1.16â€œChallengeâ€ means, with respect to a Patent Right, that Gemma or a Sublicensee (including sub-Sublicensees) will be deemed to have made a â€œChallengeâ€ of such Patent Rights if Gemma or such Sublicensee (including sub-Sublicensees), respectively: (a) institutes or voluntarily joins as a party to, or causes its counsel to institute on Gemmaâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, any interference, opposition, re-examination, post-grant review or similar proceeding with respect to any such Patent Right with the US Patent and Trademark Office or any foreign patent office; or (b) makes any filing or institutes or voluntarily joins as a party to any legal proceeding, or causes its counsel to make any filing or institute or voluntarily join as a party to any legal proceeding on Gemmaâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, with a court or other Governmental Body (including, without limitation, the US Patent and Trademark Office or any foreign patent office) having authority to determine the validity, enforceability or scope of such Patent Right, in which one or more claims or allegations challenges the validity or enforceability of any such Patent Right.1.17â€œChange of Controlâ€ with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:(a)any Third Party â€œpersonâ€ or â€œgroupâ€ (as such terms are defined below) (i) is or becomes, through one or a series of transactions, the â€œbeneficial ownerâ€ (as defined below), directly or indirectly, of the then-outstanding shares of common stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total then-outstanding common stock (or foreign equivalent thereof) (the â€œOutstanding Common Stockâ€), (ii) is or becomes, through one or a series of transactions, the â€œbeneficial ownerâ€, directly or indirectly, of shares of securities, capital stock or other interests (including partnership interests) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) then-outstanding and normally entitled (without regard to the 3â€‹â€‹occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions (â€œOutstanding Voting Stockâ€) of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) representing fifty percent (50%) or more of the total voting power of all Outstanding Voting Stock of such Party (or any direct or indirect parent entity or ultimate parent entity of such Party), or (iii) has the power, directly or indirectly, to elect a majority of the members of the Partyâ€™s (or any direct or indirect parent entities or ultimate parent entities of such Party) board of directors (or similar governing body); or(b)such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) enters into a merger, consolidation or similar transaction with a Person (whether or not such Party (or any direct or indirect parent entity or ultimate parent entity of such Party) is the surviving entity) (a â€œBusiness Combinationâ€), in each case, unless, following such Business Combination, (i) the individuals and entities who were the beneficial owners, respectively, of the Outstanding Common Stock and Outstanding Voting Stock of such Party (and the ultimate parent entity thereof) immediately prior to such Business Combination beneficially own, directly or indirectly, fifty percent (50%) or more of, respectively, (1) the then-outstanding shares of common stock (or foreign equivalent thereof) and (2) the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of directors, of the corporation or other entity resulting from such Business Combination (and the ultimate parent entity thereof), and (ii) fifty percent (50%) or more of the members of the board of directors (or similar governing body) of the corporation or other entity resulting from such Business Combination (and ultimate parent entity thereof, as applicable) were members of the

board of directors (or similar governing body) of such Party (or ultimate parent entity of such Party, as applicable) at the time of the execution of the initial agreement, or became members of the board of directors of such corporation or other entity by virtue of the action of the board of directors (or similar governing body) of such Party (or ultimate parent entity), providing for such Business Combination; or(c)such Party (and its Affiliates) sells, exchanges, or otherwise transfers to any Third Party, directly or indirectly (including through the transfer of shares or other ownership interests in Affiliates), in one or a series of transactions, the properties and assets representing all or substantially all of such Partyâ€™s total assets (together with all or substantially all of the properties and assets of its Affiliates).For the purpose of this definition of Change of Control, (x) â€œpersonâ€ and â€œgroupâ€ have the meanings given such terms under Sections 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term â€œgroupâ€ includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act; (y) a â€œbeneficial ownerâ€ shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms â€œbeneficially ownedâ€ and â€œbeneficially ownâ€ shall have meanings correlative to that of â€œbeneficial owner.â€1.18â€œClinical Studyâ€ means a Phase 1 Study, Phase 1/2 Study, Phase 2 Study, or Phase 3 Study, or such other study in humans that is conducted in accordance with cGCP and is designed to generate data in support or maintenance of an application for Regulatory Approval.1.19â€œCombination Productâ€ means a Licensed Product that is delivered with [*] active 4â€‹â€‹ingredients or other items or services incident to the administration of any such Licensed Product (with or without [*] such other active ingredients), [*], in each such case when any of the foregoing are co-formulated, co-packaged or sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).1.20â€œCommercializeâ€ means any and all activities directed to the offering for sale and sale of a pharmaceutical or biological product, including activities directed to marketing, promoting, advertising, detailing, storing, distributing, importing, exporting, selling, and offering to sell (including receiving, accepting, and filling orders), booking and recording sales, interacting with Regulatory Authorities regarding any of the foregoing and seeking Pricing and Reimbursement Approvals. Â â€œCommercializationâ€ and â€œCommercializingâ€ have a corresponding meaning.1.21â€œCommercially Reasonable Effortsâ€ means the efforts and resources that a similarly situated biotechnology company would use for its own internally discovered technology of similar commercial potential at a similar stage of development, taking into account the likely timing of the technologyâ€™s entry into the market and any patent and other proprietary position, safety and efficacy, product profile, and the then-current competitive and regulatory environments for the product. Â Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the performing Party (a) promptly assign responsibility for such obligation to specific employee(s) who are accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.1.22â€œCompeting Productâ€ means any product other than a Licensed Product for use in the Indication in the Field of Use.1.23â€œCompetitive Infringementâ€ has the meaning set forth in Section 8.6.1.1.24â€œCompulsory Licenseâ€ means a compulsory license under the Licensed UPenn Patents obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in any country.1.25â€œConfidential Informationâ€ has the meaning set forth in Section 7.1.1.26â€œControlâ€ means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without (i) violating the terms of any other agreement or other arrangement with any Third Party from whom the Party or its Affiliate acquired such intellectual property rights, (ii) requiring additional obligations, liabilities or financial consideration to such Third Party in connection with the grant of such license or sublicense (other than consideration for which the Party or its Affiliate agrees to bear the entire cost), or (iii) violating the terms of, or requiring additional obligations, liabilities or financial consideration to a Third Party under, [*]. Â â€œControlledâ€ has a corresponding meaning.5â€‹â€‹1.27â€œCoverâ€ means (a) with respect to a claim of an issued Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof), or (b) with respect to a claim of a pending Patent Right and a compound or product, that the manufacture, use, offer for sale, sale or importation of such compound or product would, if such claim were to issue in its current form, infringe such claim in the country in which such activity occurs (absent a license to or ownership thereof). Â â€œCoveredâ€ has a corresponding meaning.1.28â€œCROâ€ means a Third Party contract resesarch organization (for clarity, excluding consultants).1.29â€œCT Enrollment Dateâ€ means the earlier of (a) the date upon which Gemma, or any of its Affiliates or Sublicensees, either directly or through a contractor, opens enrollment at a site for a Clinical Study for a Licensed Product under this Agreement, or (b) the date upon which Gemma, or any of its Affiliates or Sublicensees, either directly or through a contractor, opens enrollment at a site for a Clinical Study for a Licensed Product (as defined in the Krabbe License Agreement) under the Krabbe License Agreement.1.30â€œData Protection Lawsâ€ has the meaning set forth in Section 9.3.1.1.31â€œDevelopâ€ means any and all pre-clinical, non-clinical and clinical research and development activities for a pharmaceutical or biological product, including activities related to preclinical research and studies, Clinical Studies, toxicology, pharmacokinetic, pharmacodynamic, drug-drug interaction, safety, tolerability and pharmacological studies, supply of such product for use in the foregoing activities (including placebos and comparators), statistical analyses, the preparation and submission of INDs, MAAs and other Regulatory Materials for the purpose of obtaining, registering and maintaining Regulatory Approval of such product, as well all interactions with Regulatory Authorities with respect to the foregoing. Â â€œDevelopingâ€ and â€œDevelopmentâ€ have a corresponding meaning.1.32â€œDevelopment Milestone Eventâ€ has the meaning set forth in Section 5.2.1.33â€œDevelopment Milestone Paymentâ€ has the meaning set forth in Section 5.2.1.34â€œDisputeâ€ has the meaning set forth in Section 12.6.1.1.35â€œDivestitureâ€ means, with respect to a Competing Product, (a) [*] (i) [*], or (ii) [*], or (b) [*] with respect to such Competing Product. Â [*]. Â â€œDivestâ€ has a corresponding meaning.1.36â€œElectronic Deliveryâ€ has the meaning set forth in Section 12.13.1.37â€œEMAâ€ means the European Medicines Agency and any successor entity thereto.1.38â€œEnforcement Actionâ€ means a legal action to enforce the Licensed UPenn Patents with respect to Competitive Infringement.1.39â€œEuropean Unionâ€ or â€œEUâ€ means the European Union.6â€‹â€‹1.40â€œExclusivity Periodâ€ has the meaning set forth in Section 3.1.1.41â€œExecutive Officersâ€ means Gemmaâ€™s Chief Executive Officer, or her or his designee, and Passageâ€™s Chief Executive Officer, or her or his designee, provided that any such designee must have decision-making authority on behalf of the applicable Party.1.42â€œFD&C Actâ€ means the United States Federal Food, Drug and Cosmetic Act, as amended.1.43â€œFDAâ€ means the United States Food and Drug Administration and any successor entity thereto.1.44â€œField of Useâ€ means all prophylactic, diagnostic and therapeutic uses in humans. Â For clarity, [*].1.45â€œFirst Commercial Saleâ€ means, on a country-by-country basis, the first commercial transfer or disposition for value of a Licensed Product in such country to a Third Party by Gemma, or any of its Affiliates or Sublicensees, in each case, after Regulatory Approval for such Licensed Product has been obtained for such country.1.46â€œFPFDâ€ means, with respect to a Licensed Product and a Clinical Study, the first dosing of the first patient in such Clinical Study.1.47â€œFTEâ€ means an individual employee of Passage or its Affiliates.1.48â€œGAAPâ€ means United States generally accepted accounting principles applied on a consistent basis.1.49â€œGemma Collaboration Know-Howâ€ means any and all Arising Know-How.1.50â€œGemma Collaboration Patentsâ€ means any and all Patent Rights that claim Gemma Collaboration Know-How.1.51â€œGemma Indemniteeâ€ has the meaning set forth in Section 10.2.1.52â€œGeneric Productâ€ means, with respect to a particular Licensed Product in a particular country or regulatory jurisdiction, a generic or biosimilar pharmaceutical product, that is not produced, licensed or owned by Gemma, any of its Affiliates or Sublicensees, that: (a) is bioequivalent or biosimilar to such Licensed Product; and (b) is approved for use in such country or regulatory jurisdiction by a Regulatory Authority by referencing the prior approval, in whole or part, or safety and efficacy data submitted in support of the prior approval, of a Licensed Product. Â Generic Product includes, but is not limited to, any pharmaceutical products for which Regulatory Approval is obtained via: (i) a bioequivalence or bioavailability showing such as those covered by section 505(j) of the FD&C Act or an equivalent outside the United States; or (ii) a biosimilarity or interchangeability determination such as those covered by section 351(k) of the PHS Act or an equivalent outside the United States.1.53â€œGovernmental Bodyâ€ means any: (a) nation, principality, state, commonwealth, 7â€‹â€‹province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.1.54â€œINDâ€ means an Investigational New Drug Application as defined in the FD&C Act and the regulations promulgated thereunder, or the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, including a Clinical Trial Authorization to the European Medicines Agency, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.1.55â€œIndemnified Partyâ€ has the meaning set forth in Section 10.3.1.1.56â€œIndemnifying Partyâ€ has the meaning set forth in Section 10.3.1.1.57â€œIndicationâ€ means Metachromatic leukodystrophy through [*]. 1.58â€œKnow-Howâ€ means any proprietary or confidential scientific or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form, including inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know-how, trade secrets, skill, experience, test data and other information and technology applicable to formulations, compositions or products or to their manufacture, development, registration, use, marketing or sale or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, physical and analytical, safety, quality control data, manufacturing, and stability data, studies and procedures, and manufacturing process and development information, results and data. Â Know-How excludes Materials and Patent Rights.1.59â€œKrabbe License Agreementâ€ has the meaning set forth in the recitals.1.60â€œLawâ€ or â€œLawsâ€ means all applicable laws, statutes, rules, regulations, ordinances, and other pronouncements having the binding effect of law of any Governmental Body.1.61â€œLicenseâ€ has the meaning set forth in Section 2.1.1.62â€œLicensed Compoundâ€ means PBML04, as more fully described in Schedule 1.62.1.63â€œLicensed Know-Howâ€ means the Licensed UPenn Know-How and Passage Know-How.1.64â€œLicensed Product(s)â€ means any (a) process, service or method covered by a Valid Claim of a UPenn Patent or whose use or practice would, absent the License, constitute an 8â€‹â€‹infringement, inducement of infringement or contributory infringement of any Valid Claim of a UPenn Patent, or would infringe a Valid Claim of a UPenn Patent once issued (â€œMethodâ€); (b) article, composition, apparatus, substance, chemical or any other material covered by a Valid Claim of a UPenn Patent or whose manufacture, import, use, offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim of a UPenn Patent or would infringe a Valid Claim of a UPenn Patent once issued; (c) service, article, composition, apparatus, chemical, substance or any other material made, used or sold by or utilizing or practicing a Method, or (d) any product that incorporates or makes use or is made through use of UPenn Know-How or Passage Know-How, in each case (a) through (d), for the Indication. Â Notwithstanding the foregoing, the Licensed Products shall include any product containing or comprising the Licensed Compound (alone or in the form of a Combination Product) in all forms, presentations, formulations, methods of administration and dosages.1.65â€œLicensed UPenn Know-Howâ€ means all UPenn Know-How that is necessary to Develop, Manufacture or Commercialize the Licensed Products for the Indication.1.66â€œLicensed UPenn Patentsâ€ means all UPenn Patents that are necessary to Develop, Manufacture or Commercialize the Licensed Products for the Indication.1.67â€œLossesâ€ has the meaning set forth in Section 10.1.1.1.68â€œMAAâ€ means (a) a Biologics License Application (as defined in the PHS Act) or New Drug Application (as defined in the FD&C Act) filed with the FDA to gain approval to market a biological or pharmaceutical product in the US, (b) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure to gain approval to market a biological or pharmaceutical product in the EU, or (ii) a Regulatory Authority in any EU country if the centralized EMA filing procedure is not used to gain approval to market a biological or pharmaceutical product in the EU, or (c) any equivalent application or request for authorization filed in support of approval to market a biological or pharmaceutical product in any country, in each case ((a) through (c)), including any amendments and supplements thereto but excluding applications for Pricing and Reimbursement Approval.1.69â€œMajor Marketâ€ means United States, Japan, France, Germany, Spain, Italy, and the United Kingdom.1.70â€œManufactureâ€ means all activities in connection with the manufacture of a pharmaceutical or biological product, including the processing, formulating, testing (including quality control, quality assurance and lot release testing), bulk packaging, filling, finishing, packaging, labeling, inspecting, receiving, storage, release, shipping and delivery, sourcing of materials, process qualification, validation and optimization, and stability testing of such product. Â â€œManufacturingâ€ and â€œManufacturedâ€ have a corresponding meaning.1.71â€œMaterialsâ€ means any and all biological and other physical materials.1.72â€œNet Salesâ€ means the gross consideration invoiced or received by Gemma or any of its Affiliates or Sublicensees (including all sub-Sublicensees) for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less 9â€‹â€‹the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary:(a)trade discounts, including trade, cash and quantity discounts or rebates, credits, or refunds;(b)allowances or credits actually granted upon claims, returns or rejections of products;(c)charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the Sale, transportation, delivery or return of such Licensed Product;(d)customs duties, sales, excise and use taxes actually paid in connection with the transportation, distribution, use or Sale of such Licensed Product (but excluding what is commonly known as income taxes); and(e)bad debt expense and amounts actually written off by reason of uncollectible debt not to exceed [*] of the Net Sales of Licensed Product.Even if there is overlap between any of the deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation.In the case of a Combination Product, the Parties shall negotiate in good faith, at the latest [*] before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, as the case may be, based on the fair market value of such components for the purposes of determining a product-specific allocation of such Net Sales. Â Payments related to such Combination Product under this Agreement, including Royalties and milestone payments, will be calculated, due and payable based only on the portion of such Net Sales so allocated to a Licensed Productâ€™s components.In case of disagreement and failure by the Parties to agree upon an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, [*].1.73â€œNew License Agreementâ€ has the meaning set forth in Section 11.7.2.1.74â€œNon-Exclusively Licensed Penn IPâ€ has the meaning set forth in Section 2.1.1.75â€œPassage Indemniteeâ€ has the meaning set forth in Section 10.1.1.1.76â€œPassage Know-Howâ€ means all Know-How Controlled by Passage or any of its Affiliates as of the Effective Date that is necessary to Develop, Manufacture or Commercialize the Licensed Compound for the Indication other than any Licensed UPenn Know-How.1.77â€œPassage Technologyâ€ means the Licensed Know-How and Licensed Patents.10â€‹â€‹1.78â€œPatent Right(s)â€ means (a) patents and patent applications, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part, reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing, and (b) all official correspondence relating to the foregoing.1.79â€œPatent Term Extensionâ€ has the meaning set forth in Section 8.3.1.80â€œPersonâ€ means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.1.81â€œPersonal Dataâ€ has the meaning set forth in Section 9.3.1.1.82â€œPhase 1 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. Â§312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. Â The drug candidate can be administered to patients as a single agent or in combination with other investigational or marketed agents.1.83â€œPhase 1/2 Studyâ€ means a clinical study of a drug candidate in diseased human patients that satisfies the requirements of a Phase 1 Study and a Phase 2 Study.1.84â€œPhase 2 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. Â§312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States, including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. Â§312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. Â§312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Clinical Study (e.g., a Phase 1/2 Study). Â The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.85â€œPhase 3 Studyâ€ means a clinical study of a drug candidate in human

patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. Â The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.86â€œPHS Actâ€ means the United States Public Health Service Act, as amended.1.87â€œPricing and Reimbursement Approvalâ€ means, in a country or other jurisdiction where the Governmental Bodies of such country or jurisdiction approve or determine the price that 11â€‹â€‹can be charged for a pharmaceutical or biological product in such country or jurisdiction, or that can be reimbursed by Governmental Bodies for such product in such country or jurisdiction, (a) the approval, agreement, determination, or decision by the relevant Governmental Bodies establishing the price that can be legally charged to consumers for such product in such country or jurisdiction, or (b) the approval, agreement, determination, or decision by the relevant Governmental Bodies establishing the level of reimbursement that will be reimbursed by Governmental Bodies for such product in such country or jurisdiction.1.88â€œProgram Regulatory Materialsâ€ means any and all Regulatory Materials specific to the Licensed Products that are Controlled by Gemma or any of its Affiliates on or after the Effective Date (including, without limitation, the Regulatory Materials transferred from Passage to Gemma pursuant to the Transition Services Agreement).1.89â€œProgress Reportâ€ has the meaning set forth in Section 6.8.1.1.90â€œProsecute and Maintainâ€ means activities directed to (a) preparing, filing, prosecuting and maintaining Patent Rights, (b) managing and settling any interference, opposition, re-issue, reexamination, supplemental examination, invalidation (including inter partes or post-grant review proceedings), revocation, nullification or cancellation proceeding relating to the foregoing, but excluding managing and settling the defense of challenges to Patent Rights in a declaratory judgment action or as part a counterclaim in an infringement proceeding.1.91â€œQualified Financingâ€ means the next financing, or series of financings, after the Effective Date in which Gemma receives at least [*] in the aggregate, but excluding any non-dilutive financing.1.92â€œRegulatory Approvalâ€ means, with respect to a pharmaceutical or biological product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use, marketing, and sale of such pharmaceutical or biological product in such jurisdiction in accordance with Laws. Â â€œRegulatory Approvalâ€ does not include authorization by a Regulatory Authority to conduct named patient, compassionate use, or other similar activities.1.93â€œRegulatory Authorityâ€ means any Governmental Body, including the FDA, or EMA, or any successor agency thereto, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical or biological product in any country.1.94â€œRegulatory Exclusivityâ€ means, with respect to a given pharmaceutical or biological product and a given country or other jurisdiction, a period of exclusivity (other than exclusivity due to Patent Rights) granted or afforded under Law or by a Regulatory Authority in such country or other jurisdiction that prevents the Regulatory Approval or marketing of any Generic Product of such product in such country, such as new chemical entity, orphan drug or pediatric exclusivity granted or afforded pursuant to the FD&C Act.1.95â€œRegulatory Materialsâ€ means all (a) applications (including all INDs, MAAs and applications for Pricing and Reimbursement Approval), registrations, licenses, authorizations and approvals (including Regulatory Approvals and Pricing and Reimbursement Approvals), (b) 12â€‹â€‹correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files, (c) supplements or changes to any of the foregoing, and (d) clinical and other data, including Clinical Study data, contained or relied upon in any of the foregoing.1.96â€œRegulatory Submissionsâ€ means all Regulatory Materials submitted to a Regulatory Authority in support of the Development, Manufacture or Commercialization of a pharmaceutical or biological product.1.97â€œResearch Programâ€ means the development program for Licensed Products in and for the Indication in the Field of Use to be conducted by Gemma hereunder in accordance with the applicable development plan therefor.1.98â€œRoyaltyâ€ has the meaning set forth in Section 5.4.1.1.99â€œRoyalty Termâ€ means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period beginning on the First Commercial Sale of such Licensed Product in such country and continuing until the latest of: (a) the expiration of the last Valid Claim of the last Licensed UPenn Patent that Covers such Licensed Product in such country, (b) ten (10) years after the First Commercial Sale of such Licensed Product in such country, and (c) termination or expiration of all Regulatory Exclusivities for such Licensed Product in such country.1.100â€œSaleâ€ means any transaction for which consideration is received or invoiced by Gemma, its Affiliates or Sublicensees for sale, use, lease, transfer, or other disposition of a Licensed Product to or for the benefit of a Third Party. Â For clarity, sale, use, lease, transfer, or other disposition of a Licensed Product by Gemma or any of its Affiliates or Sublicensees to another of these entities for resale (or other disposition) by such entity to a Third Party shall not be deemed a Sale.1.101â€œSales Milestone Eventâ€ has the meaning set forth in Section 5.3.1.102â€œSales Milestone Paymentâ€ has the meaning set forth in Section 5.3.1.103â€œSDR Reportâ€ has the meaning set forth in Section 2.3.2.1.104â€œSecurities Regulationâ€ has the meaning set forth in Section 7.5.2.1.105â€œSecurities Regulatorâ€ has the meaning set forth in Section 7.5.2.1.106â€œSegregateâ€ means, with respect to a Competing Product, to use reasonable efforts to segregate the Development, Manufacturing and Commercialization of the Competing Product from the Development, Manufacturing and Commercialization of a Licensed Product, including [*]; provided that applicable personnel within a Partyâ€™s (or its Affiliatesâ€™) financial functions may review financial information with respect to the Competing Product as necessary to comply with its financial oversight and reporting obligations.1.107â€œSpecified Obligationsâ€ means the licenses, options, and obligations that Passage 13â€‹â€‹or Penn has granted or owes to a Third Party that are identified in ExhibitÂ A, [*].1.108â€œSubcontractorâ€ has the meaning set forth in Section 2.4.1.109â€œSublicense Documentsâ€ means any and all agreements, amendments or written understandings entered into with a Sublicensee (including any of its Affiliates) that are directly or indirectly related to a Sublicense, Passage Technology, or Licensed Product. Â For clarity, a development agreement or distribution agreement for a Licensed Product is a Sublicense Document.1.110â€œSublicenseeâ€ means a Person (including any Affiliate) to which a Sublicense, including sub-Sublicensees, is granted pursuant to the terms of Section 2.3.1.1.111â€œTaxâ€ means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body.1.112â€œTermâ€ has the meaning set forth in Section 11.1.1.113â€œTerritoryâ€ means worldwide.1.114â€œThird Partyâ€ means any Person, other than a Party or an Affiliate of a Party.1.115â€œThird Party Claimâ€ has the meaning set forth in Section 10.1.1.1.116â€œThird Party Infringement Claimâ€ has the meaning set forth in SectionÂ 8.7.1.1.117â€œTransition Services Agreementâ€ means that certain transition services agreement to be executed by the Parties as of the Effective Date.1.118â€œUnited Statesâ€ or â€œUSâ€ means the United States of America, its territories and possessions.1.119â€œUPenn Agreementâ€ has the meaning set forth in the recitals.1.120â€œUPenn Letter Agreementsâ€ means (a) that certain letter agreement between Passage and Penn dated [*], and (b) that certain letter agreement between Passage and Penn dated [*].1.121â€œUPenn Patentsâ€ means all Patent Rights Controlled by Passage or any of its Affiliates that have been licensed to Passage under the UPenn Agreement and that are related to the Indication. Â The UPenn Patents existing as of the Effective Date are listed on Schedule 1.121 hereto.1.122â€œUPenn Know-Howâ€ means all Know-How Controlled by Passage or any of its Affiliates that have been licensed to Passage under the UPenn Agreement and that is related to the Indication.14â€‹â€‹1.123â€œUS Bankruptcy Codeâ€ has the meaning set forth in Section 11.4.2.1.124â€œUSD,â€ â€œDollars,â€ or â€œ$â€ means United States dollars.1.125â€œValid Claimâ€ means, with respect to Patent Rights, a claim of (a) an issued and unexpired patent in such Patent Rights which claim has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no further appeal can be taken or has been taken within the time allowed for appeal, and has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer; or (b) a pending patent application (that has been pending for no more than [*] from the filing date of such application) that is included in such Patent Rights which was filed and is being prosecuted in good faith, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.Article 2â€‹LICENSE2.1Exclusive License to Gemma. Â Subject to the terms and conditions of this Agreement, during the Term, Passage, on behalf of itself and its Affiliates, hereby grants to Gemma an exclusive (even as to Passage and its Affiliates), transferable (solely in accordance with SectionÂ 12.1), sublicensable (solely in accordance with SectionÂ 2.3), royalty-bearing license under the Passage Technology to make, have made, use, sell, offer for sale and import the Licensed Products for the Indication in the Field of Use in the Territory; provided that, to the extent any Passage Technology is non-exclusively licensed to Passage by Penn (â€œNon-Exclusively Licensed Penn IPâ€), the license granted by Passage to Gemma under such Non-Exclusively Licensed Penn IP shall be exclusive solely with respect to Passageâ€™s interest in such Non-Exclusively Licensed Penn IP (the â€œLicenseâ€).2.2Retained Rights. Â Notwithstanding the exclusive nature of the License, Passage retains the rights to practice the Passage Technology solely to perform its obligations under this Agreement and the UPenn Agreement.2.3Right to Sublicense.2.3.1Passage grants to Gemma the right to grant sublicenses, in whole or in part, under the License (each, a â€œSublicenseâ€) subject to the terms and conditions of this Agreement and specifically this Section 2.3. Â The term â€œSublicenseâ€ shall include any grant of rights under the License by a Sublicensee to any downstream Third Party, provided such downstream Third Party shall also be considered a Sublicensee for purposes of this Agreement.2.3.2All Sublicenses will (a) be issued in writing, (b) to the extent applicable, include all of the rights of Passage and require the performance of obligations due to Passage (and, if applicable, Penn and the U.S. Government under 35 U.S.C. Â§Â§200-212) contained in this Agreement, and (c) include no less than the following terms and conditions:(a)Reasonable record keeping, audit and reporting obligations sufficient to enable Gemma and Passage to reasonably verify the payments due to Gemma, Penn and Passage under such Sublicense and to reasonably monitor such Sublicenseeâ€™s progress in 15â€‹â€‹Developing or Commercializing Licensed Product; provided that such obligations shall be no less stringent that those provided in this Agreement for Gemma.(b)Infringement and enforcement provisions that do not conflict with the restrictions and procedural requirements imposed on Gemma and do not provide greater rights to Sublicensee than as provided in Section 8.6.(c)Confidentiality provisions with respect to Confidential Information of Passage and Penn consistent with the restrictions on Gemma in Article 7 of this Agreement.(d)Covenants by Sublicensee that are equivalent to those made by Gemma in Sections 9.3 and 9.5.(e)A requirement of indemnification of Passage and Penn by Sublicensee that is equivalent to the indemnification of Passage by Gemma under Sections 10.1.1 and 10.1.2 of this Agreement and of Penn by Gemma under Section 10.1.3 of this Agreement.(f)A requirement of obtaining and maintaining insurance by Sublicensee that is equivalent to the insurance requirements of Gemma under Section 10.4 of this Agreement, including coverage under such insurance of Passage and Penn as provided in Section 10.4.(g)Restriction on use of Passageâ€™s and Pennâ€™s names, etc. consistent with Section 7.6 of this Agreement.(h)A requirement of antidiscrimination by Sublicensee no less stringent than that provided in Section 12.3 of this Agreement.(i)A requirement that Passage and Penn are third party beneficiaries of such Sublicense.Any Sublicense that does not include all of the terms and conditions set forth in this Section 2.3.2 or which is not issued in accordance with the terms and conditions set forth in this Section 2.3, shall be considered null and void with no further notice from Passage unless separately approved by Passage in writing.Within [*] after the execution of a Sublicense Document, Gemma shall provide a complete and accurate copy of such Sublicense Document to Passage, in the English Language. Â Passageâ€™s receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Passage or obligation of Gemma under this Agreement.Gemma and its Sublicensees shall provide an annual Sublicense Development Report on or before [*] of each year during the Term (â€œSDR Reportâ€), a form of which is attached hereto as ExhibitÂ B.2.4Right to Subcontract. Â Each Party may subcontract the performance of any of its obligations under this Agreement to one or more Third Party subcontractors engaged for the purpose of Development, Manufacture or Commercialization of the Licensed Products as set forth 16â€‹â€‹herein (each such Third Party a â€œSubcontractorâ€). Â All such Subcontractors shall be subject to a written agreement that is consistent with the applicable terms and conditions of this Agreement and must meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity, including entering into such Partyâ€™s standard nondisclosure agreement consistent with Article 7 and the ownership and management of intellectual property rights. Â Each Party shall remain responsible and liable to the other Party for the performance of all Subcontractors to the same extent as if such activities were conducted by such Party. Â Any Party engaging a Subcontractor hereunder will remain responsible and obligated for such activities and will not grant rights to such Subcontractor that interfere with the rights of the other Party under this Agreement.2.5Right of Access and Reference. Â 2.5.1Gemma hereby grants to Passage a right of reference to all Program Regulatory Materials in the Territory solely for [*]. Â 2.5.2Passage hereby grants to Gemma a right of reference to all Regulatory Materials Controlled by Passage or its Affiliates in the Territory solely for [*]. Â 2.5.3Each Party will take such actions as may be reasonably requested by the other Party to give effect to the intent of this Section 2.5, including providing a cross-reference letter or similar communication to the applicable Regulatory Authority to effectuate such right of access and reference.2.6No Implied Licenses. Â Except as expressly set forth in this Agreement, neither Party nor its Affiliates, by virtue of this Agreement, shall acquire any license, right or other interest, whether by implication or otherwise, in or to any Know-How, Patent Rights, Regulatory Materials, Materials or other intellectual property rights owned or controlled by the other Party or its Affiliates.2.7Upstream License. Â To the extent any Passage Technology licensed to Gemma pursuant to the License includes a sublicense to Patent Rights or Know-How licensed to Passage or its Affiliates under the UPenn Agreement, the Parties acknowledge and agree that such sublicensed Passage Technology is subject to the terms and conditions of the UPenn Agreement. Â Gemma agrees to abide by all terms and conditions of the UPenn Agreement as they relate to Gemma as a Sublicensee under such agreement and notwithstanding anything in this Agreement to the contrary, in the event of any conflict between the terms hereof and the terms of the UPenn Agreement as they relate to Gemma as a Sublicensee under the UPenn Agreement, the terms of the UPenn Agreement shall govern. Â Gemma shall timely take all actions reasonably necessary or requested by Passage, including timely providing to Passage all information reasonably necessary, for Passage to comply with its obligations under the UPenn Agreement. Â Without limiting the foregoing, Gemma shall provide to Passage the information necessary for Passage to comply with any royalty or milestone reporting obligations under the UPenn Agreement. Without limiting Section 5.8, Gemma shall be solely responsible for [*] of all amounts payable by Passage under the UPenn Agreement on and after the Effective Date (including milestone payments and royalties) incurred as a result of Gemmaâ€™s exercise of its rights under this Agreement.17â€‹â€‹2.7.1Penn Retained Rights. Â Without limiting Section 2.7 and notwithstanding the exclusive nature of the License, Gemma acknowledges and agrees that the License is subject to Pennâ€™s rights under the UPenn Agreement, including:(a)Pennâ€™s right to (i) conduct educational, research, clinical activities, and patient care activities itself, including, but not limited to sponsored research, and (ii) authorize non-commercial Third Parties to conduct educational, research and clinical activities and patient care activities, all as more fully described in the UPenn Agreement; and(b)any applicable requirement, order, written request, or decree by a Regulatory Authority to Penn to make any Patent Rights, Know-How, or Materials available to a Third Party on a non-exclusive basis.2.7.2U.S. Government Rights. Â Without limiting Section 2.7 and notwithstanding the exclusive nature of the License, Gemma acknowledges and agrees that the License is expressly subject to all applicable provisions of any license to the United States Government executed by Penn and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. Â§Â§200-212, applicable governmental implementing regulations, and U.S. Government sponsored research agreement or other guidelines, including that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States.2.8Third Party Licenses. Â Gemma shall have the right, in its sole discretion, to negotiate and obtain licenses or other rights to Third Party Know-How, Patent Rights or other rights in connection with its Development, Manufacture or Commercialization of the Licensed Products in the Territory, and, if applicable, Section 5.4.2(c) shall apply to any amounts payable to such Third Party with respect to any such license or right.Article 3â€‹EXCLUSIVITY3.1Exclusivity. Â During the period of [*] after the Effective Date (the â€œExclusivity Periodâ€), Gemma will not, and will ensure that its Affiliates and Sublicensees do not (a) [*], or (b) [*], in each case (a) and (b), other than Commercialization of the Licensed Products in accordance with the terms of this Agreement.3.2Exception for Change of Control. Â Notwithstanding Section 3.1, if:3.2.1Gemma or any of its Affiliates acquires any Competing Product or the rights to research, develop, manufacture or commercialize any Competing Product anywhere in the Territory in each case through the acquisition of a Third Party (whether by merger or acquisition of all or substantially all of the stock or assets of a Third Party or of any operating or business division of a Third Party or similar transaction), then such acquisition, and the research, development, manufacture or commercialization of such Competing Product thereafter, shall not constitute a breach of Section 3.1 if Gemma or such Affiliate, as applicable, Divests such Competing Product within [*] after the closing of such acquisition and at all times Segregates such Competing Product prior to such Divestiture; and18â€‹â€‹3.2.2Gemma undergoes a Change of Control and the Acquiror (or its Affiliate) is at the time of the closing of such Change of Control researching, developing, manufacturing or commercializing a Competing Product anywhere in the Territory, then such Change of Control, and the research, development, manufacture or commercialization of such Competing Product by such Acquiror or its Affiliate, shall not constitute a breach of Section 3.1 if such Acquiror or its Affiliate Divests such Competing Product within [*] after the closing of such Change of Control and at all times Segregates such

Competing Product prior to such Divestiture.Article 4â€‹GOVERNANCE4.1Alliance Managers. Â Each Party will appoint a representative to act as its alliance manager under this Agreement (each, an â€œAlliance Managerâ€). Â Each Alliance Manager will be responsible for promoting effective communication between the Parties and shall be the primary point of contact between the Parties.4.2Cooperation with UPenn Agreement Committees.4.2.1General. Â During the Term, Gemma shall provide Passage with all reasonable assistance, at Passageâ€™s request, for Passage to respond to any request by Penn or under any committee formed under the UPenn Agreement, including preparing relevant reports and responses, providing access to relevant documents, and other evidence, and making its employees reasonably available during business hours as necessary, in each case at Gemmaâ€™s cost and expense. Â Passage shall use Commercially Reasonable Efforts to seek Gemmaâ€™s comments with respect to any such request (including to the extent permissible, seeking a representative of Gemmaâ€™s attendance at any such committee meeting and discussing in good faith any materials submitted thereto with respect to the Licensed Products).4.2.2Updates to Existing JSCs. Â Without limiting Section 4.2.1, during the Term, upon Passageâ€™s reasonable request, Gemma shall provide an update to the development plan delivered under Section 6.1 for the Licensed Products describing the status of the clinical development thereof, for Passageâ€™s and Pennâ€™s review.Article 5â€‹PAYMENTS5.1Product Supply; Upfront Fee. As partial consideration for the License and other rights granted by Passage to Gemma herein, and in exchange for Passageâ€™s supply of product for the conduct of a Clinical Study for a Licensed Product by Gemma or its designee, Gemma shall pay to Passage (a) [*], and (b) [*].5.2Development and Regulatory Milestones. Â Upon the first achievement by Gemma, its Affiliate or a Sublicensee of each development and regulatory milestone event set forth in the table below (each a â€œDevelopment Milestone Eventâ€), Gemma shall make the corresponding one-time, non-refundable, non-creditable payment set forth in the table below (each a â€œDevelopment Milestone Paymentâ€) to Passage in accordance with Section 5.5.1.Development Milestone EventDevelopment Milestone 19â€‹â€‹Payment (USD)[*][*][*][*]Total[*]If any of the above Development Milestone Events are skipped (such that a later Development Milestone Payment becomes due and payable before an earlier Development Milestone Payment), then the skipped Development Milestone Event(s) will be deemed to have been achieved upon the achievement of the subsequent Development Milestone Event, and the Development Milestone Payment(s) corresponding to such skipped Development Milestone Event(s) shall be due and payable at the same time as the subsequent Development Milestone Event.5.3Sales Milestones. Â Upon the first achievement of each sales-based milestone event set forth in the table below (each, a â€œSales Milestone Eventâ€), Gemma shall make the corresponding one-time, non-refundable, non-creditable payment set forth in the table below (each a â€œSales Milestone Paymentâ€) to Passage in accordance with Section 5.5.1.Sales Milestone EventSales Milestone Payment (USD)[*][*][*][*][*]Total[*]Each of the foregoing Sales Milestone Payments in this Section 5.3 shall be payable a maximum of one (1) time hereunder regardless of the number of times the applicable Sales Milestone Event is achieved. Â For the avoidance of doubt, the aggregate maximum amount payable by Gemma under this Agreement pursuant to this Section 5.3 is [*]. Â In the event that in a given Calendar Year more than one (1) Sales Milestone Event is achieved, Gemma shall pay to Passage the Sales Milestone Payment with respect to each such Sales Milestone Event.5.4Royalty Payments.5.4.1Royalty Payments for Licensed Products. Â Subject to the remainder of this Section 5.4, on a Licensed Product-by-Licensed Product basis, during the Royalty Term for such Licensed Product, Gemma shall pay Passage a [*] royalty on aggregate annual Net Sales of such Licensed Product in the Territory (the â€œRoyaltyâ€), calculated by multiplying [*] by the aggregate annual Net Sales of all Licensed Products in the Territory. Â Such payments, and associated reports, shall be made in accordance with Section 5.5.2.5.4.2Royalty Reductions.(a)No Valid Claim. On a country-by-country basis, if at any time during the Royalty Term for a Licensed Product in such country there is no Valid Claim of the 20â€‹â€‹Licensed UPenn Patents that Covers such Licensed Product in such country and such Licensed Product is not subject to Regulatory Exclusivity, then (i) the royalty rate set forth in Section 5.4.1 for such Licensed Product shall be permanently reduced in such country by [*] for the remainder of such Royalty Term, and (ii) no Royalty at all will apply to such Licensed Product [*].(b)Compulsory License. Â In the event that Gemma or Passage receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. Â If any Third Party obtains a Compulsory License in any country, then: (i) Gemma or Passage (whoever has first notice) shall promptly notify the other Party; and (ii) beginning as of the date the Third Party obtained such Compulsory License in such country, the Royalty rate payable under Section 5.4.1 to Passage for Net Sales in such country will be adjusted to equal any lower Royalty rate granted to such Third Party for such country with respect to the sales, use, lease, transfer or other disposition of such Licensed Product by such Third Party therein.(c)Third Party Payments. If, after the Effective Date, Gemma determines upon the advice of outside intellectual property counsel that a license to Patent Rights from a Third Party is reasonably necessary to develop, commercialize, or manufacture a Licensed Product in a particular country, Gemma may obtain such Third Party license to such Patent Rights. Â Gemma may deduct from any Royalty payments due to Passage under Section 5.4.1 an amount equal to [*] of any Royalty paid by Gemma to a Third Party on Sales of a particular Licensed Product in a particular country during a Calendar Quarter under a Third Party license obtained by Gemma for such country, pursuant to this Section 5.4.2(b).(d)Generic Product. In the event that one or more Generic Product(s) with respect to a particular Licensed Product enter(s) the market in a particular country, and such Generic Product(s) in the aggregate have a market share of [*] or more in that country, Gemma may reduce the Royalty payments for Sales of such Licensed Product in such country by [*]; provided that if Gemma reduces the Royalty payments under this Section 5.4.2(d), Gemma shall resume making Royalty payments without reduction under this Section 5.4.2(d) as of the earlier of (a) no Generic Product being sold for at least [*] in such country, and (b) a court of competent jurisdiction determines that a Valid Claim of a Licensed UPenn Patent is valid and infringed by such Generic Product in such country.(e)Cumulative Reductions Floor. In no event will the amount of Royalties due to Passage for a Licensed Product in any given Calendar Quarter be reduced as a result of the reductions set forth in Sections 5.4.2(c) and 5.4.2(d) (cumulatively) by more than [*] of the amount that otherwise would have been due and payable to Passage in such Calendar Quarter for such Licensed Product.5.4.3Royalty Payments. Â Gemma shall pay Royalties owed to Passage on a Calendar Quarter basis on or before the following dates:(a)[*] for any Sales that took place in the Calendar Quarter ending DecemberÂ 31, of the prior Calendar Year;(b)[*] for any Sales that took place in the Calendar Quarter ending MarchÂ 31 of such Calendar Year;21â€‹â€‹(c)[*] for any Sales that took place in the Calendar Quarter ending JuneÂ 30 of such Calendar Year; and(d)[*] for any Sales that took place in the Calendar Quarter ending September 30 of such Calendar Year.5.5Payment Terms.5.5.1Milestone Payments. Â Gemma shall promptly notify Passage in writing upon the occurrence of a Development Milestone Event or Sales Milestone Event and Gemma shall pay Passage in full the corresponding non-refundable Development Milestone Payment or Sales Milestone Payment within [*] after such occurrence.5.5.2Royalty Reports. Â Within [*] after the end of each Calendar Quarter, Gemma shall deliver to Passage (or at Passageâ€™s written direction, Penn) a report (â€œFinancial Reportâ€) setting out all details necessary to calculate the Royalty due under this Article 5 for such Calendar Quarter, including:(a) [*];(b)Gross sales and Net Sales of each Licensed Product made by Gemma, its Affiliates and Sublicensees (including sub-Sublicensees);(c)Royalties;(d)The method and currency exchange rates (if any) used to calculate the Royalties;(e)A specification of all deductions and their dollar value that were taken to calculate Net Sales;(f)A list of all countries in which Licensed Product is being manufactured (on a Licensed Product-by-Licensed Product basis); and(g)The date of First Commercial Sale in the United States (this need only be reported in the first Financial Report following such First Commercial Sale in the United States).Each Financial Report shall be in the form of the sample report attached hereto as ExhibitÂ C.5.6Payment Currency; Exchange Rate; Offset. Â All payments to be made under this Agreement shall be made in USD. Â Payments to a Party shall be made by electronic wire transfer of immediately available funds to the account of the other Party, as designated in writing to the paying Party. Â If any currency conversion is required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the average of the rates quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter for which such payment is made. Â Gemma shall not have the right to offset any payment that is owed by Gemma 22â€‹â€‹to Passage but not yet paid against any payments owed by Passage to Gemma under this Agreement.5.7Late Payments. Â Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to the lesser of: (a) [*] per month or (b) the maximum rate permitted by Law; in each case calculated on the number of days such payment is delinquent, compounded monthly. Â In the event of a default in payment of any payment owing under the terms of this Agreement, and if it becomes necessary for Passage to undertake legal action to collect said payment, Gemma shall pay reasonable, documented legal fees and costs incurred in connection therewith.5.8Payments to Third Parties. Â Gemma shall be solely responsible for [*] of all amounts payable by Passage under the UPenn Agreement on and after the Effective Date (including milestone payments and royalties) incurred as a result of Gemmaâ€™s exercise of its rights under this Agreement. Â Gemma shall pay such amounts to Passage in accordance with this Article 5 (unless otherwise directed by Passage in writing to make payments directly to such licensor), in each case, no later than [*] prior to the date on which the applicable amount is due and payable by Passage under the UPenn Agreement. Â Without limiting the foregoing, Gemma shall promptly (but in any event not more than [*] thereafter) provide notice to Passage upon the achievement (by Gemma, its Affiliates or Sublicensees) of any of the third party milestones set forth in ExhibitÂ D and pay the corresponding milestone amount owed under the UPenn Agreement, as provided by Passage to Gemma, to Passage (unless otherwise directed by Passage in writing to make payments directly to Penn) no later than [*] following the achievement of such milestone. Â At the request of Gemma, Passage shall use Commercially Reasonable Efforts to seek applicable and available reductions of any royalties owed under the UPenn Agreement.5.9Accounting. Â Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.5.10Records and Audit Rights.5.10.1Records. Â Gemma will keep accurate books and records of all Licensed Products developed, manufactured, used, or sold and all Sublicenses, collaboration agreements and joint venture agreements entered into by Gemma that involve Passage Technology. Â Gemma will preserve these books and records for at least [*] from the date of the Financial Report to which they pertain. Â Upon reasonable notice, key personnel, books, and records will be made reasonably available and will be open to examination by representatives or agents of Passage or Penn during regular office hours to determine their accuracy and assess Gemmaâ€™s compliance with the terms of this Agreement and the UPenn Agreement; provided that Gemma shall not have an obligation to provide access more than once in any given [*] period to Passage.5.10.2Audit. Â In addition to the right of Passage and Penn to examine the books and records and interview key personnel as provided in Section 5.10.1, Passage or Penn (each an â€œAuditing Partyâ€), at its own cost, through an independent auditor reasonably acceptable to Gemma (and who has executed an appropriate confidentiality agreement reasonably acceptable to Gemma that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to the Auditing Party), may inspect and audit the relevant 23â€‹â€‹records of Gemma pertaining to the calculation of any payments due hereunder (including any Development Milestone Payments, Sales Milestone Payments, or Royalties). Â Gemma shall provide such auditors with access to the records during reasonable business hours. Â Such access need not be given to any such set of records more often than once each year for a given Auditing Party or more than [*] after the date of any report to be audited. Â The Auditing Party shall provide Gemma with written notice of its election to inspect and audit the records related to the payments due hereunder not less than [*] prior to the proposed date of review of Gemmaâ€™s records by the Auditing Partyâ€™s auditors. Â Should the auditor find any underpayment by Gemma, Gemma shall (a) promptly pay Passage (or at Passageâ€™s written direction, Penn) the amount of such underpayment; (b) shall reimburse the Auditing Party for the cost of the audit, if such underpayment equals or exceeds the higher of (i) [*] or (ii) [*] of all payments paid to Passage (or with respect to Penn, the amount owed under the UPenn Agreement) during the time period audited; and (c) provide such auditors with an audit right exercisable within [*] after such Auditing Party receives the audit report. Â If the auditor finds overpayment by Gemma, then Gemma shall have the right to deduct the overpayment from any future income due to Passage (or with respect to Penn, the amount owed under the UPenn Agreement) or, if no such future payments are due hereunder (or with respect to Penn, future payments due under the UPenn Agreement) shall refund the overpayment to Gemma within [*] after the Auditing Party receives the audit report; provided that to the extent any amounts owed to Gemma relate to the UPenn Agreement, Passage shall refund the overpayment to Gemma within [*] after receiving payment for such overpayment from Penn, if not paid directly to Gemma.5.11Taxes. All payments made by Gemma to Passage (or Passageâ€™s designee) under this Agreement shall be made free and clear of and without any deduction for or on account of any Taxes on or with respect to such payments.5.12Blocked Currency. Â If due to Law in a country or other jurisdiction in the Territory, conversion into USD or transfer of funds of a convertible currency to the United States becomes materially restricted, forbidden or substantially delayed, then Gemma shall promptly notify Passage and, thereafter, amounts accrued in such country or other jurisdiction under this Article 5 (other than Section 5.8) shall be paid to Passage (or its designee) in such country or other jurisdiction in local currency by deposit in a local bank designated by Passage and to the credit of Passage, unless the Parties otherwise agree. For clarity, [*].Article 6â€‹DEVELOPMENT AND COMMERCIALIZATION6.1Development Plan. Gemma shall provide Passage or its designee with a development plan (or updated development plan) no later than [*] of each year during the Term. Â The development plan shall include a timeline for detailed activities to be conducted by Gemma, its Affiliates and Sublicensees, and Gemma shall provide Passage with [*] progress reports regarding achievements and activities under such development plan. Â Subject to Section 6.2, [*].6.2Clinical Development. Â Gemma shall have the first right to sponsor all clinical activities and lead regulatory interactions for the Licensed Products, and will be solely responsible for the associated costs of such Development. Â Gemma will consider in good faith using Penn as a study site for one or more Clinical Studies where Penn can reasonably demonstrate that Pennâ€™s 24â€‹â€‹capabilities and costs are reasonably comparable to other potential study sites. Â If Penn (in its sole discretion) is willing and able to conduct a Clinical Study for a Licensed Product developed under the Research Program, the Parties and Penn will negotiate a separate clinical trial agreement and a separate clinical trial budget prior to initiation of such Clinical Study; provided that any such study shall be at Gemmaâ€™s cost and expense.6.3Commercialization. Gemma will have sole responsibility for and sole decision-making over the Commercialization of the Licensed Products for the Indication in the Field of Use, and will be solely responsible for the associated costs of such Commercialization.6.4Manufacturing. Â Gemma will have sole responsibility for and sole decision-making authority over all Manufacturing of the Licensed Products for the Indication in the Field of Use.6.5Regulatory. Â Gemma will have responsibility for and decision-making over regulatory activities for the Licensed Products for the Indication in the Field of Use. Â Gemma will have the right to conduct all communications with Regulatory Authorities, including all meetings, conferences, and discussions (including advisory committee meetings), with regard to Licensed Products for the Indication in the Field of Use; provided, [*]. Â Gemma will lead and have control over preparing and submitting all Regulatory Submissions related to the Licensed Products for the Indication in the Field of Use, including all MAAs, provided, however, that Gemma shall provide Passage (or at Passageâ€™s written request, Penn) with copies of all such applications prior to submission, to the extent such submission includes any Confidential Information of Passage. Â Gemma will own any and all Regulatory Materials, Regulatory Submissions (including INDs), and Regulatory Approvals related to the Licensed Products for the Indication in the Field of Use, which will be held in the name of Gemma or its designees.6.6General Diligence. Gemma will use Commercially Reasonable Efforts to actively Develop, obtain Regulatory Approval for and Commercialize at least one Licensed Product for the Indication in the Field of Use.6.7Diligence Events.6.7.1General. Â Gemma shall achieve each of the diligence events set forth in ExhibitÂ E (each a â€œDiligence Eventâ€) by the corresponding achievement date (each a â€œAchievement Dateâ€). Â Gemma acknowledges that the achievement of each Diligence Event by the corresponding achievement date is a condition of the UPenn Agreement. Â The timeline for each Achievement Date is based on the assumption that Development and Commercialization of the Licensed Products does not encounter material regulatory or other delays for reasons outside of Gemmaâ€™s reasonable control. Â Where such circumstances exist, Passage agrees to negotiate in good faith with Gemma and Penn (on Gemmaâ€™s behalf), upon Gemmaâ€™s written request and provided such request is made at least [*] prior to the Achievement Date for a Diligence Event, an extension of the Achievement Date for a Diligence Event for such Licensed Products as reasonably requested by Gemma. Â If the Parties and Penn have not agreed on a requested extension within [*] of Passageâ€™s notice to Penn of such request, then upon either Gemmaâ€™s or Pennâ€™s written request, Passage and Penn [*]. Â For clarity, [*].25â€‹â€‹6.7.2Review. Â Gemma acknowledges that if, following a review requested by Penn under Section 4.2.2, Penn in good faith reasonably believes that Gemma has not materially funded any activities to advance the Development of the Licensed Products during any [*], Penn may submit such matter for arbitration by an arbitrator selected in accordance with Section 6.7.1 to determine whether Gemma has failed to materially fund any such activities. Â The Parties shall use Commercially Reasonable Efforts to cooperate with each other with respect to any such arbitration (including to the extent permissible, seeking a representative of Gemmaâ€™s attendance at any hearing and discussing in good faith any materials submitted thereto with respect to the Licensed Products). Â All costs and expenses incurred by Passage with respect to such arbitration (including its reasonable legal fees) shall be reimbursed by Gemma within [*] of an invoice therefor. Â Gemma acknowledges and agrees that, if (i) the arbitrator finds that Gemma (on behalf of Passage) has failed to materially fund any such activities as set forth above, and (ii) Gemma does not cure such failure to materially fund within [*] of the arbitratorâ€™s determination, then, notwithstanding anything in this Agreement to the contrary, Passage will have the right to terminate this Agreement with immediate effect upon written notice to Gemma.6.8Progress Reports.6.8.1Prior to the First Commercial Sale of a Licensed Product, on an annual basis but in no event later than [*] of each Calendar Year, Gemma shall submit to Passage (or at

Passageâ€™s written direction, Penn) a progress report (each, a â€œProgress Reportâ€) covering Gemmaâ€™s (and any Affiliatesâ€™ and Sublicenseesâ€™) activities related to the Development of all Licensed Products and the obtaining of Regulatory Approvals necessary for Commercialization of Licensed Products.6.8.2Each Progress Report must include all of the following for each annual period:(a)Summary of material Development activities;(b)Summary of material Commercialization activities;(c)Identification of filings for Regulatory Approval and other material correspondence with Regulatory Authorities;(d)An updated SDR Report listing any and all Sublicenses granted by Gemma; and(e)The names and addresses of all Sublicensees, and a current and valid phone number and e-mail address for a principal point of contact at each such Sublicensee who is responsible for administering the Sublicensee.Article 7â€‹CONFIDENTIALITY7.1Confidential Information. Â For purposes of this Agreement, â€œConfidential Informationâ€ of a Party means any and all confidential or proprietary information, data, or materials, including all Know-How and other scientific, pre-clinical, clinical, regulatory, 26â€‹â€‹manufacturing, marketing, financial and commercial information or data, whether or not patentable and in any form (written, oral, photographic, electronic, magnetic, or otherwise), including information of Third Parties, that such Party (or an Affiliate or representative of such Party) discloses or otherwise makes available to the other Party (or to an Affiliate or representative of the other Party) in connection with this Agreement. Â The Passage Technology shall be the Confidential Information of Passage, and the terms and conditions of this Agreement shall be the Confidential Information of both Parties.7.2Duty of Confidence; Exceptions. Â Each Party agrees that, during the Term and for a period of [*] thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement (including for the exercise of the rights and licenses granted to such Party hereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. Â The foregoing confidentiality and non-use obligations shall not apply with respect to any information that the receiving Party can demonstrate by competent written proof:7.2.1was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed by the disclosing Party to the receiving Party, or was otherwise developed independently by or for the receiving Party without use of or reference to the disclosing Partyâ€™s Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;7.2.2was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party, as evidenced by written records of the receiving Party;7.2.3became generally available to the public or otherwise part of the public domain after its disclosure other than through any act or omission of the receiving Party in breach of this Agreement; or7.2.4was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.Any combination of features shall not be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the receiving Party.7.3Authorized Disclosures. Â Notwithstanding Section 7.2, the receiving Party may disclose the disclosing Partyâ€™s Confidential Information if and to the extent such disclosure is reasonably necessary in the following instances:7.3.1subject to Section 7.5, to comply with Law;7.3.2to its external attorneys, independent accountants, or financial advisors solely for the purpose of enabling such attorneys, independent accountants, or financial advisors to provide advice to it; and27â€‹â€‹7.3.3to its Affiliates, employees, consultants, and agents and actual or potential Sublicensees (in the case of Gemma), collaborators, actual or potential investors, or contractors, as applicable and as may be needed to exercise its rights or perform its obligations in accordance with the terms of this Agreement;provided that in each of the cases of Sections 7.3.1-7.3.3 such Person is subject to a written agreement containing obligations of confidentiality and non-use at least as stringent as those herein (or without such agreement for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement).Notwithstanding the foregoing, in the event that a Party is required to make a disclosure of the other Partyâ€™s Confidential Information pursuant to SectionsÂ 7.3.1 and 7.3.3, it will, except where impracticable, promptly inform the other Party of the disclosure that is being sought in order to provide the other Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Partyâ€™s efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the other Partyâ€™s expense. Â In any such event, each Party agrees to take all reasonable actions to minimize disclosure of the other Partyâ€™s Confidential Information. Â Any information disclosed pursuant to this Section 7.3 shall remain, subject to Section 7.2, the Confidential Information of the disclosing Party and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 7.7.4Prior Confidentiality Agreements. Â This Agreement supersedes that certain Mutual Confidentiality Agreement between the Parties effective as of [*] (the â€œCDAâ€). Â All information exchanged between the Parties under the CDA shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 7.7.5Public Disclosures; Securities Filings.7.5.1Press Release. Â Each Party agrees not to issue any press release or other public statement, whether oral or written, disclosing the terms hereof or any of the activities conducted hereunder without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed); provided, however, that (a) neither Party shall be prevented from complying with any duty of disclosure it may have pursuant to Securities Regulations, (b) either Party may make subsequent public disclosure of the contents of any such approved press release or other public statement, and (c) Passage shall have the right to make public announcements regarding the achievement of any material events regarding the progress of the Development and Commercialization of a Licensed Product under this Agreement, as well as the achievement of Development Milestone Events or Sales Milestone Events, or the receipt of any payments hereunder.7.5.2Securities Filings. Â Notwithstanding anything herein to the contrary, a Party or its Affiliates may disclose the relevant terms of this Agreement to the extent required or advisable to comply with the rules and regulations promulgated by the US Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory (such rules and regulations â€œSecurities Regulationsâ€ and each such agency a â€œSecurities Regulatorâ€). Â If a 28â€‹â€‹Party is required by Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator, such Party agrees to reasonably consult and coordinate with the other Party with respect to such disclosure and, if applicable, the preparation and submission of a confidential treatment request for this Agreement. Â Notwithstanding the foregoing, if a Party is required by Law to submit a description of the terms of this Agreement to or file a copy of this Agreement with any Securities Regulator and such Party has (i) promptly notified the other Party in writing of such requirement and any respective timing constraints, (ii) provided copies of the proposed disclosure or filing to the other Party reasonably in advance of such filing or other disclosure, and (iii) given the other Party a reasonable time under the circumstances to comment upon and request confidential treatment for such disclosure, then such Party will have the right to make such disclosure or filing at the time and in the manner reasonably determined by its counsel to be required by Law or the applicable Securities Regulator. Â If a Party seeks to make a disclosure or filing as set forth in this Section 7.5.2 and the other Party provides comments within the respective time periods or constraints specified herein, the Party seeking to make such disclosure or filing will reasonably consider such comments and use good faith efforts to incorporate such comments in the disclosure or filing; provided that prior to making any such filing of this Agreement, the Parties shall reasonably cooperate and use good faith efforts to agree on a redacted form of this Agreement to be so filed.7.6Use of Names. Â Gemma, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Passage, Penn or any Penn school, organization, employee, student or representative, without the prior written consent of Passage or Penn, as applicable. Â Notwithstanding the foregoing, Gemma may use the name of Passage or Penn in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by Gemma for the purpose of raising financing for the operations of Gemma as related to Licensed Product, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Passage Technology (subject to the provisions of Article 7) have been licensed by Gemma from Passage and sublicensed by Gemma from Penn, and/or to inform a reader of the identity and published credentials of inventors of intellectual property, and (b) any securities reports required to be filed with a Securities Regulator in the US.Article 8â€‹INTELLECTUAL PROPERTY8.1Ownership. Â Inventorship of Arising Know-How and all intellectual property rights therein shall be determined in accordance with principles of inventorship for Patent Rights and other intellectual property under US law, and ownership shall follow inventorship.8.2Patent Prosecution and Maintenance.8.2.1Licensed UPenn Patents. Â Gemma acknowledges that the Prosecution and Maintenance of the Licensed UPenn Patents shall be controlled by Penn. Â Passage shall use Commercially Reasonable Efforts to cooperate with Gemma to provide any comments to such Prosecution and Maintenance of the Licensed UPenn Patents to Penn, as allowable under the UPenn Agreement. Â Gemma will bear all amounts required to be paid to Penn under the UPenn Agreement during the Term for the Prosecution and Maintenance of the Licensed UPenn Patents.29â€‹â€‹8.2.2Gemma Collaboration Patents. Â As between the Parties, Gemma shall have the sole right, but not the obligation, to Prosecute and Maintain the Gemma Collaboration Patents in the Territory, at Gemmaâ€™s cost and expense.8.3Cooperation for Patent Extensions. Â [*].8.4Patent Listings. Â Passage shall have the sole right to list or de-list the UPenn Patents in the FDAâ€™s â€œPurple Bookâ€ or any equivalent thereto in any country in the Territory with respect to the Licensed Products. Â Gemma shall reasonably cooperate with Passage in making or withdrawing any such listing for a Passage Patent, including executing all necessary documents to implement such patent listing, at its cost and expense.8.5Common Interest Disclosures. Â With regard to any information or opinions exchanged pursuant to this Agreement by the Parties (or their Affiliates) regarding intellectual property owned by Third Parties, the Parties agree that they have a common legal interest in coordinating Prosecution and Maintenance of their respective Patent Rights, as set forth in this Article 8, and in determining whether, and to what extent, Third Party intellectual property rights may affect the conduct of the Development, Manufacturing or Commercialization of the Licensed Products, and have a further common legal interest in defending against any actual or prospective Third Party claims based on allegations of misuse or infringement of intellectual property rights relating to the Development, Manufacturing or Commercialization of the Licensed Products. Â Accordingly, Gemma and Passage agree that all such information and materials obtained by Gemma or Passage from each other will be used solely for purposes of the Partiesâ€™ common legal interests with respect to the conduct of this Agreement. Â All information and materials will be treated as protected by the attorney-client privilege, the work product privilege and any other privilege or immunity that may otherwise be applicable. Â By sharing any such information and materials, neither Party intends to waive or limit any privilege or immunity that may apply to the shared information and materials. Â Neither Party shall have the authority to waive any privilege or immunity on behalf of the other Party without such other Partyâ€™s prior written consent, nor shall the waiver of privilege or immunity resulting from the conduct of one Party be deemed to apply against the other Party.8.6Patent Enforcement.8.6.1Notice. Â Each Party shall notify the other within [*] after becoming aware of any alleged or threatened infringement by a Third Party of any UPenn Patent or Gemma Collaboration Patent (an â€œInfringement Noticeâ€), which infringement adversely affects or could reasonably be expected to adversely affect the Development, Manufacture or Commercialization of any Licensed Product for the Indication in the Field of Use in the Territory, or any related declaratory judgment or equivalent action alleging the invalidity, unenforceability or non-infringement of any such Patent Right (each a â€œCompetitive Infringementâ€).8.6.2Gemma Collaboration Patents. Â As between the Parties, Gemma shall have the sole right, but not the obligation, to enforce the Gemma Collaboration Patents or take any steps to abate an alleged or actual Third Party infringement of any Gemma Collaboration Patent anywhere in the Territory, at Gemmaâ€™s sole cost and expense.30â€‹â€‹8.6.3Licensed UPenn Patents.(a)Notification of Infringement. Â Gemma shall [*] without first obtaining the written consent of Passage, which consent will not be unreasonably withheld, conditioned or delayed. Â If Gemma [*], then Gemmaâ€™s right to request Passage initiate an Enforcement Action under Section 8.6.3(b) below will terminate immediately without the obligation of Passage to provide notice to Gemma. Â Passage and Gemma will use their diligent efforts to cooperate with each other and Penn to terminate such infringement without litigation.(b)Request for Enforcement. Â If the Competitive Infringement of a UPenn Patent has not been abated within [*] following the date the Infringement Notice was provided and during the period in which, and in the jurisdiction where, Passage is exclusively licensed under such infringed UPenn Patent (such UPenn Patent, during such period and in such jurisdiction, the â€œExclusive Penn Patent Rightsâ€), then Gemma may, but no later than [*] following the date of the Infringement Notice, request Passage to institute an Enforcement Action of an Exclusive Penn Patent Right against the infringer. Â Following receipt of such request, Passage shall [*]. Â Passage shall keep Gemma reasonably informed as to the status of any such Enforcement Action and shall consider in good faith the comments of Gemma with respect thereto. Â Gemma acknowledges that Passage or Penn may bring an action with respect to any such Competitive Infringement if not requested by Gemma within such [*] period following the date of the Infringement Notice.(c)Cooperation. Â In connection with any Enforcement Action under this Section 8.6.3, Gemma shall [*]. Â Gemma shall be entitled to separate representation in an Enforcement Action by counsel of its own choice and at its own cost and expense, but Gemma shall at all times cooperate fully with Passage.8.6.4Biosimilar Action. Â Notwithstanding anything to the contrary in SectionÂ 8.6.1, during the Term, each Party shall [*] give written notice to the other Party of any application for [*] (each a â€œBiosimilar Actionâ€) of which it becomes aware and referencing [*]. Â Passage shall have the sole and exclusive right, but not the obligation, to prosecute and manage any litigation with respect to any Biosimilar Action at its cost and expense, and Gemma shall cooperate fully in any such action at Passageâ€™s cost and expense.8.6.5Recoveries. Â Unless otherwise agreed to by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.6.3, or Section 8.6.4 (whether by way of settlement or otherwise) shall [*] with respect to such action ([*]), and any remaining recovery amount shall [*], provided [*]. Â Unless otherwise agreed by the Parties in writing, the amount of any recovery from a proceeding brought under Section 8.6.2 shall [*].8.7Infringement of Third Party Rights.8.7.1Notice. Â Each Party shall promptly notify the other Party in writing within [*] after receiving a notice of a claim or assertion that any Licensed Product, or any Passage Technology, infringes or misappropriates any Third Partyâ€™s Patent Rights or other intellectual property rights in any country (â€œThird Party Infringement Claimâ€), which notice shall include a copy of any summons or complaint (or the equivalent thereof), including, if applicable, a certified 31â€‹â€‹translation into English, received regarding the foregoing. Â Thereafter, the Parties shall promptly meet to consider the Third Party Infringement Claim and the appropriate course of action and may, if appropriate, agree on and enter into a â€œjoint defense agreementâ€ wherein the Parties agree to their shared, mutual interest in the outcome of such potential dispute. Â The Parties shall assert and not waive the joint defense privilege, attorney work-product doctrine, attorney client privileges or any other privileges or protections that may apply with respect to any communications between the Parties in connection with the defense of such claim or assertion.8.7.2Defense. Â Unless the alleged infringing Party seeks indemnification for a Third Party Infringement Claim pursuant to Section 10.1 or Section 10.2, as between the Parties, the alleged infringing Party shall [*]. Â Neither Party shall enter into any settlement of any such Third Party claim that materially adversely affects the other Partyâ€™s rights or interests under this Agreement or imposes any obligation or liability on the other Party without the other Partyâ€™s prior written consent (or with respect to Gemma, that materially adversely affects Pennâ€™s rights or interests in the Licensed UPenn Patents or imposes any obligation or liability on Penn without Passageâ€™s prior written consent).8.8Patent Marking. Â Gemma shall mark all Licensed Products in accordance with applicable patent marking laws and shall require all of its Affiliates and Sublicensees to do the same.8.9Trademarks. Â Gemma will solely own all right, title and interest in and to any trademarks adopted for use with the Licensed Products for the Indication in the Field of Use in the Territory, and will be responsible for the registration, filing, maintenance and enforcement thereof. Â Neither Passage nor any of its Affiliates will at any time do or authorize to be done any act or thing which is likely to materially impair the rights of Gemma therein, and will not at any time claim any right of interest in or to such marks or the registrations or applications therefor. Â Neither Passage nor any of its Affiliates will use Gemmaâ€™s or any of its Affiliatesâ€™ trademarks or any trademark that is confusingly similar thereto.Article 9â€‹REPRESENTATIONS, WARRANTIES, AND COVENANTS9.1Representations and Warranties of Each Party. Â Each Party represents and warrants to the other as of the Effective Date that:9.1.1such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;9.1.2such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;9.1.3this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditorsâ€™ rights generally and by general equitable principles; and32â€‹â€‹9.1.4such Party has all right, power and authority to enter into this Agreement and to perform its obligations under this Agreement.9.2Representations and Warranties of Passage. Â Passage represents and warrants to Gemma as of the Effective Date that:9.2.1it Controls all of the UPenn Patents;9.2.2it has received no written notice or allegation, and has no other reasonable basis to believe, that any of the Licensed UPenn Patents are invalid or unenforceable, or that the use, development, practicing or exploitation of any Licensed UPenn Patents infringes the Patent Rights of any Third Party (provided, for clarity, that this Section 9.2.2 will not be construed as requiring Passage to discover, or to conduct any investigation regarding, the Patent Rights of any Third Party of which Passage has no actual knowledge and with respect to which it has not received any written notice or allegation);9.2.3it has not granted any license or option rights nor made any contractual commitments that are inconsistent with the rights granted to Gemma

hereunder;9.2.4to the knowledge of Passage, the License includes all available Patent Rights Controlled by Passage that are necessary for the Development, Manufacture and Commercialization of the Licensed Products for the Indication in the Field of Use in the Territory.9.3Mutual Covenants. Â Each Party covenants to the other Party that in the course of performing its obligations or exercising its rights under this Agreement, such Party shall, and shall cause its Affiliates, Sublicensees and subcontractors to, comply with Law, including, as applicable, cGMP, cGLP and cGCP. Â Without limiting the foregoing, the Parties additionally agree as follows:9.3.1Data Privacy. Â Each Party shall: (a) comply with Law in relation to data protection, privacy, or restrictions on, or requirements in respect of, the processing of Personal Data of any kind, including the Health Insurance Portability and Accountability Act, General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR), and any equivalent Law in any other jurisdiction (as any of the foregoing may be amended from time to time, collectively, â€œData Protection Lawsâ€) with respect to the collection, use, transfer, storage, destruction, aggregation or other use of subject health information or other Personal Data (as defined in the applicable Data Protection Laws, collectively, â€œPersonal Dataâ€) in connection with its activities under or in connection with this Agreement, including the Development and Commercialization of any Licensed Product hereunder; (b) implement appropriate and reasonable security processes and controls in connection with its activities under or in connection with this Agreement so as to protect the security and privacy of Personal Data in accordance with Data Protection Laws; and (c) take such steps as necessary to comply with Data Protection Laws to permit such Party to disclose Personal Data to the other Party and to permit the other Party to use and disclose such Personal Data for its own purposes in accordance with this Agreement. Â Without limiting the foregoing, if required by Law, the Parties will negotiate and enter into a written agreement with respect to the collection, storage, transfer, processing and use of Personal Data by the Parties and their Affiliates as contemplated by this Agreement.33â€‹â€‹9.3.2No Debarment or Regulatory Sanction. Â Neither Party shall employ (or, knowingly use any contractor, subcontractor, distributor or other Person that provides services to such Party in connection with this Agreement that employs) any Person that is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority (including, as applicable, the FDA pursuant to its authority under SectionsÂ 306(a) andÂ (b) of the FD&C Act) or that is the subject of any investigation or proceeding which may result in debarment, disqualification, blacklisting, banning or any similar sanction by any applicable Regulatory Authority, in each case, in connection with the performance of its activities under this Agreement. Â Each Party shall notify the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred, disqualified, blacklisted, banned or subject to any similar sanction by any applicable Regulatory Authority or becomes the subject of any such investigation or proceeding.9.4Passage Covenants. Â Passage hereby covenants to Gemma during the Term that (a) it shall, and shall cause its Affiliates to, remain in compliance in all material respects with the UPenn Agreement, and it shall promptly provide to Gemma any written notice received from or provided to the counterparty to the UPenn Agreement that relates to Gemmaâ€™s rights or obligations hereunder, including any notice of breach or default, and (b) it will not (and will cause its Affiliates not to), without Gemmaâ€™s prior written consent, grant to any Third Party any license or other right, or any lien or security interest, with respect to any of the Passage Technology in a manner that would conflict with or impair any of the rights or licenses granted to Gemma hereunder.9.5Gemma Covenants. Â Gemma hereby covenants to Passage that it shall, and shall cause its Affiliates, Sublicensees and subcontractors to (a) not directly or indirectly (including where the same is done by a Third Party on behalf of Gemma or its Affiliates, at the urging of Gemma or its Affiliates or with the assistance of Gemma or its Affiliates) institute or make any Challenge of any Licensed UPenn Patents; provided, however, that if any Licensed UPenn Patent is asserted against Gemma or its Affiliates for activities authorized under this Agreement, then Gemma or its Affiliates (or the Sublicensee or sub-Sublicensee) is entitled to all and any defenses available to it including challenging the validity or enforceability of such Patent Right; (b) comply with all Laws that apply to its activities or obligations under this Agreement (e.g., Gemma will comply with applicable United States export laws and regulations) and Gemma acknowledges and agrees the transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Gemma that Gemma will not export data or commodities to certain foreign countries without the prior approval of the agency; and (c) not grant a security interest in any Licensed UPenn Patents.9.6No Other Warranties.9.6.1EXCEPT AS EXPRESSLY SET FORTH HEREIN, (A) NO REPRESENTATION OR WARRANTY WHATSOEVER IS MADE OR GIVEN BY OR ON BEHALF OF PASSAGE, GEMMA, OR THEIR RESPECTIVE AFFILIATES; AND (B) ALL OTHER WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, ARE EXPRESSLY DISCLAIMED BY THE PARTIES, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT. Â PASSAGE MAKES NO WARRANTY, EITHER EXPRESS OR IMPLIED, THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF 34â€‹â€‹THE LICENSED COMPOUND OR LICENSED PRODUCTS WILL BE SUCCESSFUL OR ACHIEVE ANY PARTICULAR RESULT.9.6.2Furthermore, nothing in this Agreement will be construed as:(a)A representation or warranty by Passage as to the validity or scope of any Licensed UPenn Patents;(b)A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;(c)Obligating Passage to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement; and(d)Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Passage other than the Licensed UPenn Patents as defined herein, regardless of whether such Patent Rights are dominant or subordinate to the Licensed UPenn Patents.9.6.3Gemma acknowledges and agrees that it has conducted diligence relating to the Passage Technology, and has been offered the opportunity to ask representatives of Passage questions about the Passage Technology. Â Passage represents that it has provided such available information as Licensee has requested relating to such Passage Technology and any additional available information that Passage knows to be material to the diligence conducted by Gemma.Article 10â€‹INDEMNIFICATION10.1Indemnification by Gemma.10.1.1Indemnification of Passage. Â Gemma shall defend, indemnify and hold Passage, its Affiliates and their respective directors, officers, employees, contractors and agents (the â€œPassage Indemniteesâ€) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneysâ€™ fees), including, bodily injury, risk of bodily injury, death and property damage (collectively, â€œLossesâ€) arising out of Third Party claims or suits (each, a â€œThird Party Claimâ€) related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; (b) any breach of this Agreement by Gemma; or (c) the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Gemma or its Affiliates or Sublicensees; except, in each case (a)-(c), to the extent such Losses arise out of any conditions set forth in Sections 10.2(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 10.2.35â€‹â€‹10.1.2Indemnification of Passage under the UPenn Agreement. Â Without limiting Section 10.1.1, Gemma shall defend, indemnify and hold the Passage Indemnitees harmless from and against any and all Losses related to either (or both) of the UPenn Letter Agreements or a breach of the UPenn Agreement by Passage, in each case, caused by any acts or omissions of a Gemma Indemnitee; except to the extent such Losses arise out of any conditions set forth in Sections 10.2(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 10.2.10.1.3Indemnification of Penn. Â Gemma shall defend, indemnify and hold Penn and its respective trustees, officers, faculty, students, employees, contractors and agents (the â€œPenn Indemniteesâ€) harmless from and against any and all Losses arising out of a Third Party Claim related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; (b) any breach of this Agreement by Gemma; (c) the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Gemma or its Affiliates or Sublicensees; or (d) any enforcement action or suit brought by Gemma against a Third Party for infringement of any UPenn Patent; provided that Gemmaâ€™s obligations pursuant to this Section 10.1.3 shall not apply to the extent such claims or suits result from the gross negligence or willful misconduct of any of Penn Indemnitees as determined by a court of law.10.2Indemnification by Passage. Â Passage shall defend, indemnify and hold Gemma, its Affiliates and their respective directors, officers, employees, contractors and agents (the â€œGemma Indemniteesâ€) harmless from and against any and all Losses arising out of any Third Party Claim related to: (a) the negligence, recklessness or wrongful intentional acts or omissions of Passage, its Affiliates and its or their respective directors, officers, employees and agents, in connection with Passageâ€™s performance of its obligations or exercise of its rights under this Agreement; or (b) any breach of this Agreement by Passage; except, in each case (a)-(b), to the extent such Losses arise out of any conditions set forth in Sections 10.1(a)-(c) for which Gemma is obligated to indemnify any Passage Indemnitee under Section 10.1.10.3Procedure.10.3.1Notice. Â The Party seeking indemnification under Section 10.1 or SectionÂ 10.2 (the â€œIndemnified Partyâ€) shall inform the other Party (the â€œIndemnifying Partyâ€) of the Third Party Claim giving rise to the obligation to indemnify pursuant to such Section within [*] after receiving written notice of such Third Party Claim, it being understood and agreed, however, that the failure or delay by an Indemnified Party to timely give such notice shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party is actually and materially prejudiced as a result of such failure or delay to give notice.10.3.2Procedure. Â The Indemnifying Party shall assume and conduct the defense of the Third Party Claim using counsel of its choice; provided, however, that the Indemnified Party may participate in and monitor such defense with counsel of its choice at its own expense, subject to the Indemnifying Partyâ€™s right to control such defense. Â With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense: (a) the Indemnified Party shall provide 36â€‹â€‹the Indemnifying Party with reasonable assistance, at the Indemnifying Partyâ€™s expense, in connection with such defense, (b) the Indemnifying Party shall not settle any Third Party Claim without the prior written consent of the Indemnified Party if the settlement would: (i) result in or impose any obligation (including any payment obligation) on the Indemnified Party, or (ii) result in any admission of wrong-doing or fault by the Indemnified Party, and (c) so long as the Indemnifying Party is actively defending the Third Party Claim in good faith, the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party. Â If the Parties cannot agree as to the application of Section 10.1 or Section 10.2 to any Third Party Claim, pending resolution of the dispute pursuant to Section 12.6, the Parties may conduct separate defenses of such Third Party Claim(s), with each Party retaining the right to claim indemnification from the other Party in accordance with Section 10.1 or Section 10.2, as applicable, upon resolution of the underlying claim. Â If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, (A) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate, and (B) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided under Section 10.1 or Section 10.2. Â Notwithstanding anything to the contrary in this Section 10.3.2, in the event that Passage or Penn believes in good faith that a bona fide conflict exists between Gemma and Passage or Penn or any other Passage Indemnitee or Penn Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Passage or Penn or any other Passage Indemnitee or Penn Indemnitee shall have the right to defend against any such claim or suit itself, including by selecting its own counsel, with any reasonable attorneyâ€™s fees and litigation expenses being paid for by Gemma. Â Gemma will pay such fees and expenses either directly or will reimburse such Person within [*] after Gemmaâ€™s receipt of an invoice for such fees and expenses.10.4Insurance. Â Within [*] of the Effective Date, Gemma shall (and shall cause its Affiliates to) obtain commercial general liability, product liability and other appropriate insurance in an amount consistent with industry standards in light of its obligations under this Agreement, including:10.4.1Commercial Form General Liability Insurance (contractual liability included) with limits no less than as follows:(a)Each occurrence [*];(b)General aggregate [*]; and10.4.2Prior to the commencement of Clinical Studies: (a)Clinical trials liability insurance with limits no less than [*]; and10.4.3Prior to the First Commercial Sale:(a)Products liability insurance with limits no less than[*].Gemma shall (and shall cause its Affiliates and Sublicensees to) maintain such insurance (including in the amounts set forth above) during the Term and for [*] thereafter. Â Passage may 37â€‹â€‹review periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section, and has the right to require Gemma to adjust the limits in Passageâ€™s reasonable discretion.10.4.4Gemma expressly understands, however, that the coverages and limits in this Section 10.4 do not in any way limit Gemmaâ€™s liability or indemnification obligations. Â Gemmaâ€™s insurance will:(a)Be issued by an insurance carrier with an [*] or better;(b)Provide for [*] advance written notice to Passage and Penn of any modification;(c)State that Passage and Penn are endorsed as an additional insured with respect to the coverages in this Section 10.4; and(d)Include a provision that the coverages will be primary and will not participate with nor will be excess over any valid and collective insurance or program of self-insurance carried or maintained by Passage or Penn.10.4.5Gemma shall furnish to Passage (and if requested by Passage, Penn) (a) a valid certificate of insurance evidencing compliance with all requirements of this Agreement, and (b) additional insured endorsements for Gemmaâ€™s applicable policies naming Passage and â€œThe Trustees of the University of Pennsylvaniaâ€ as additional insureds. Â Gemma shall furnish both documents within [*] after the Effective Date, once per year thereafter, and at any time there is a modification in or to such insurance.10.5Limitation of Liability. Â EACH PARTY AND ITS AFFILIATES SHALL NOT BE LIABLE TO THE OTHER PARTY AND ITS AFFILIATES FOR (A) ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES, OR (B) ANY LOSS OF PROFITS OR REVENUE, IN EACH CASE (A) AND (B) ARISING FROM OR RELATING TO THIS AGREEMENT, REGARDLESS OF WHETHER SUCH CLAIM IS IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, AND REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. Â NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 10.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT (I) A PARTYâ€™S INDEMNIFICATION OBLIGATIONS UNDER SECTION 10.1 OR SECTION 10.2, OR (II) LIABILITIES ARISING FROM A PARTYâ€™S BREACH OF ITS OBLIGATIONS UNDER SECTION 3.1 OR ARTICLEÂ 7.Article 11â€‹TERM AND TERMINATION11.1Term. Â This Agreement shall be effective commencing on the Effective Date and shall expire in its entirety upon the expiration of the last to expire Royalty Term with respect to all Licensed Products and all countries (the â€œTermâ€), unless terminated earlier in accordance with this Article 11 or by mutual written agreement of the Parties. Â Following the expiration of the Royalty Term for a Licensed Product in a particular country, the License shall become non-exclusive, fully paid-up and royalty-free (subject to any payments owed under the UPenn 38â€‹â€‹Agreement in and for such country), perpetual, and irrevocable for such Licensed Product in and for such country. Â Upon the expiration of the Term, the License shall become non-exclusive, fully paid-up and royalty-free (subject to any payments owed under the UPenn Agreement), perpetual, and irrevocable in its entirety.11.2Termination for Diligence Event Failure. In the event Gemma fails to achieve any Diligence Event by the corresponding Achievement Date (as the same may be extended under this Agreement in accordance with Section 6.7) and does not cure such breach within [*] after Gemmaâ€™s receipt of written notice (or a longer period of up to [*] if the Parties mutually agree that such longer period is necessary and acceptable) to the reasonable satisfaction of Passage or Penn, as applicable, Passage shall have the right and option to terminate this Agreement, upon written notice, with immediate effect.11.3Termination for Convenience; Termination for Cause.11.3.1Gemma may, at its convenience, terminate this Agreement in its entirety or terminate a Licensed Product for the Indication in the Field of Use, upon providing at least [*] prior written notice to Passage of such intention to terminate, provided that upon termination of a Licensed Product, except as set forth in SectionÂ 11.7.3, Gemma shall cease using the License for making, using, or selling the affected Licensed Product for the Indication in the Field of Use; provided further, that Gemma may not terminate this Agreement in its entirety or terminate a Licensed Product for the Indication in the Field of Use, in either case for convenience prior to the first anniversary of the Effective Date and the full payment of the amounts due to Passage under Section 5.1.11.3.2Each Party shall have the right to terminate this Agreement immediately in its entirety upon written notice to the other Party if such other Party materially breaches this Agreement and does not cure such breach within [*] (or within [*] with respect to a breach of any payment obligation) following receipt of written notice of such breach from the non-breaching Party; provided however, that if the breach is capable of being cured, but cure of such breach cannot reasonably be effected within such [*] period, then the cure period shall be extended an additional [*] (for a total of [*] following receipt of written notice of such breach from the non-breaching Party). Â Additionally, Passage shall have the right to terminate this Agreement in its entirety (i) upon [*] written notice if Gemma fails to comply with any Laws that apply to its activities or obligations under this Agreement, which failure(s) can be remedied, and Gemma fails to remedy such lack of compliance within such [*] period, and (ii) upon written notice, with immediate effect, if Gemma grants a security interest in any Licensed UPenn Patents.11.4Termination for Bankruptcy.11.4.1Right to Terminate. Â Each Party shall have the right to terminate this Agreement effective immediately upon delivery of written notice to the other Party in the event that (a) such other Party files in any court or agency pursuant to any statute or regulation of any jurisdiction a petition in bankruptcy or insolvency or for reorganization or similar arrangement for the benefit of creditors or for the appointment of a receiver or trustee of such other Party or its assets, (b) such other Party is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within [*] of its filing, 39â€‹â€‹or (c) such other Party makes an assignment of substantially all of its assets for the benefit of its creditors.11.4.2Rights in Bankruptcy. Â All rights and licenses granted under or pursuant to this Agreement by one Party to the other Party are, and otherwise will be deemed to be, for purposes of SectionÂ 365(n) of TitleÂ 11 of the United States Code (â€œUS Bankruptcy

Codeâ€) or comparable provision of applicable bankruptcy or insolvency laws, licenses of right to â€œintellectual propertyâ€ as defined under SectionÂ 101 of the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws. Â In the event that a case under the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws is commenced by or against a Party, the other Party shall have all of the rights and elections set forth in Section 365(n) or comparable provision of applicable bankruptcy or insolvency laws to the maximum extent permitted thereby. Â The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against a Party under the US Bankruptcy Code or any comparable provision of applicable bankruptcy or insolvency laws, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in such other Partyâ€™s possession, shall be promptly delivered to such other Party (i) upon any such commencement of a bankruptcy proceeding upon such other Partyâ€™s written request therefor, unless such Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i), following the rejection of this Agreement by such Party upon written request therefor by such other Party. Â The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, including for purposes of the US Bankruptcy Code or comparable provision of applicable bankruptcy or insolvency laws: (a) the right of access to any intellectual property (including all embodiments thereof) of the licensor, or any Third Party with whom the licensor contracts to perform an obligation of such licensor under this Agreement which is necessary for the Development, Manufacture or Commercialization of the Licensed Products; (b) the right to contract directly with any Third Party described in (a) to complete the contracted work; and (c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to such licensor under this Agreement.11.5Termination for Patent Challenge. Â In the event that Gemma or any of its Affiliates or Sublicensees directly takes any action, or knowingly provides financial or other assistance (including direct legal or technical advice) to any Third Party, to challenge in a court or administrative proceeding any claim in any Licensed UPenn Patent as being invalid, unenforceable or otherwise not patentable, this Agreement shall immediately and automatically terminate in its entirety upon the initiation of such challenge, with or without any further action by Passage; provided, however, that this Agreement shall not so automatically terminate if Gemma (or its Affiliate) or such Sublicensee challenged such Licensed UPenn Patent in defense of claims asserted by or on behalf of Passage (or its Affiliate) against Gemma (or its Affiliate) or such Sublicensee, for activities authorized under this Agreement pursuant to Section 9.5(a).11.6Full Force and Effect During Notice Period. Â This Agreement shall remain in full force and effect during the period commencing on the date of notice of termination of this Agreement and ending on the effective date of termination of this Agreement, including that Gemma shall owe royalties on Net Sales of Licensed Products made during such period, and shall be obligated to make any Development Milestone Payment or Sales Milestone Payment achieved 40â€‹â€‹during such period, even if the due date of such payment comes after the effective date of termination.11.7Effect of Termination. Â Without limiting any other legal or equitable remedies that either Party may have under this Agreement, in the event of termination of this Agreement in its entirety for any reason, the terms of this Section 11.7 will apply as of the effective date of such termination.11.7.1Licenses. Â All rights and licenses granted by either Party to the other Party pursuant to this Agreement shall terminate, and, subject to Section 11.7.2, all sublicenses granted hereunder by Gemma or its Affiliates shall also terminate.11.7.2Sublicense Survival. Â Upon termination of this Agreement for any reason (other than any such termination that results in the termination of the UPenn Agreement with respect to the Indication), upon the request of any Third Party Sublicensee, Passage will enter into a direct license with such Sublicensee on the same terms as this Agreement, taking into account any differences in license scope, territory and duration of the sublicense grant and, subject to the proviso in this sentence, Passage will, and does hereby grant to each such Sublicensee, a direct license during the period from the termination of this Agreement until Passage and each such Sublicensee have entered into such direct license (each a â€œNew License Agreementâ€); provided that, at the time of such termination, (a) such Sublicensee is not in breach of its sublicense agreement with Gemma or its Affiliate, and (b) the UPenn Agreement remains in full effect with respect to the Indication. Â Under any such New License Agreement between Passage and such former Sublicensee, such former Sublicensee will be required to pay to Passage the same amounts in consideration for such direct license as Passage would have received from Gemma pursuant to this Agreement on account of such former Sublicenseeâ€™s Development or Commercialization of Licensed Products had this Agreement not been terminated. Â Under such New License Agreement, Passage will not be bound by any grant of rights broader than, and will not be required to perform any obligations other than those rights and obligations contained in this Agreement, and all applicable rights of Passage set forth in this Agreement will be included in such New License Agreement. Â Notwithstanding the foregoing, Passage will not be obligated to enter into a New License Agreement with a Third Party Sublicensee of Gemma unless such Sublicensee notifies Passage within [*] after the termination of this Agreement that it wishes to enter into a New License Agreement.11.7.3Winddown; Sell-Off. Â Gemma shall be responsible for the prompt wind-down of Gemmaâ€™s, its Affiliatesâ€™ and their respective Sublicenseesâ€™ Development, Manufacturing and Commercialization of the Licensed Products in the Territory in compliance with Law. Â Notwithstanding the foregoing, other than in the event of termination of this Agreement by Passage pursuant to Section 11.2, Section 11.3(b), or Section 11.4, and so long as the UPenn Agreement is still in effect with respect to the Licensed Products, during the [*] period following the effective date of termination, Gemma and its Affiliates and Sublicensees shall have the right to sell or otherwise dispose of all Licensed Products for the Indication then in its or their respective inventory and any in-progress inventory; provided that Gemma shall continue to make payments to Passage on Net Sales of such Licensed Products in accordance with SectionÂ 5.4, and the rights and licenses granted to Gemma hereunder shall survive to the extent necessary for Gemma (and its Affiliates and Sublicensees) to conduct such sell-off. Â Except in connection with activities 41â€‹â€‹pursuant to the foregoing, Gemma, its Affiliates and, subject to Section 11.7.2, Sublicensees shall cease all exploitation of the Licensed Products.11.8Program Reversion. Â Passage shall have, and Gemma hereby grants to Passage, effective upon termination of this Agreement for any reason other than in the event of termination of this Agreement by Gemma pursuant to [*], a worldwide, fully-paid, royalty-free, perpetual, irrevocable, sublicensable (through multiple tiers) exclusive license under any Gemma Collaboration Know-How and Gemma Collaboration Patents solely to Develop, Manufacture, and Commercialize the Licensed Products in the Indication in the Field of Use in the Territory. Â In addition, upon Passageâ€™s request in writing within [*] after the effective date of termination, subject to Section 11.7.2, Gemma shall (and shall cause its Affiliates and Sublicensees to) (i) transfer and assign to Passage or its designee all Regulatory Submissions and Regulatory Approvals Controlled by Gemma, its Affiliates or Sublicensees for the Licensed Products in the Indication in the Field of Use, and (ii) transfer, or at Passageâ€™s election, wind-down the conduct of any ongoing Clinical Studies for a Licensed Product in the Indication in the Field of Use then being conducted by Gemma, its Affiliates or Sublicensees to Passage or its designee, or (iii) subject to Section 11.7.3, transfer to Passage all inventory of Licensed Products in the Indication then Controlled by Gemma, its Affiliates or Sublicensees at the actual cost of such supply, plus any reasonable costs associated with such transfer; provided that other than in the event of termination of this Agreement pursuant to Section 11.3(b) by Gemma, all such transfers (or wind-downs) shall be at Gemmaâ€™s sole cost and expense.11.9Confidential Information. Â Upon the expiration or termination of this Agreement in its entirety, at the disclosing Partyâ€™s election, the receiving Party shall return or destroy all tangible materials to the extent comprising, bearing or containing any Confidential Information of the disclosing Party that are in the receiving Partyâ€™s or its Affiliatesâ€™ respective possession or control and provide written certification of such destruction (if applicable) to the disclosing Party; provided that the receiving Party may retain one (1) copy of such Confidential Information for its archives solely to monitor compliance with its obligations herein or may retain such Confidential Information for which it has any continuing rights; and provided further that the receiving Party shall not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures.11.10Termination Not Sole Remedy. Â Termination is neither Partyâ€™s sole remedy under this Agreement and, whether or not termination is effected by a Party and notwithstanding anything contained in this Agreement to the contrary, all other remedies in law or equity shall remain available to both Parties except as agreed to otherwise herein.11.11Survival. Â Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Â In addition, the following provisions of this Agreement shall survive expiration or termination of this Agreement: Article 1, Article 7, Article 8, Article 10, Article 11, Article 12, and Sections 2.6, 5.10, and 9.6.42â€‹â€‹Article 12â€‹MISCELLANEOUS12.1Assignment.12.1.1Generally. Â This Agreement may not be assigned or transferred by either Party in whole or in part without the prior written consent of the other Party. Â Notwithstanding the foregoing, either Party shall have the right, without the prior written consent of the other Party, to assign or transfer this Agreement or its rights and obligations hereunder to (i) its Affiliate, or (ii) its successor in interest in connection with a Change of Control. Â A Party shall notify the other Party in writing of any assignment of this Agreement by such Party within [*] thereof. Â The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the applicable Party. Â Any attempted assignment not in accordance with this Section 12.1 shall be void. Â Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.12.1.2Effect of Change of Control.(a)Whether or not this Agreement is assigned by Passage pursuant to Section 12.1.1, the Parties agree that all Patent Rights, Know-How, Regulatory Materials, Materials or other intellectual property rights of any Acquiror of Passage will be deemed not to be â€œControlledâ€ by Passage for purposes of this Agreement and will be automatically excluded from the rights licensed to Gemma under this Agreement.(b)Notwithstanding anything in Section 5.1 to the contrary, any unpaid portion of the amounts due to Passage under Section 5.1 shall become immediately due and payable to Passage upon a Change of Control.12.2Use of Affiliates. Â Either Party shall have the right to exercise its rights and perform its obligations under this Agreement through any of its Affiliates. Â In each case where a Partyâ€™s Affiliate has an obligation pursuant to this Agreement or performs an obligation pursuant to this Agreement, (a) such Party shall cause and compel such Affiliate to perform such obligation and comply with the terms of this Agreement, and (b) any breach of the terms or conditions of this Agreement by such Affiliate shall be deemed a breach by such Party of such terms or conditions.12.3No Discrimination. Â Neither Party will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.12.4Severability. Â Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.12.5Governing Law; English Language. Â This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, without reference 43â€‹â€‹to any rules of conflict of laws that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Â The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable. Â This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.12.6Dispute Resolution.12.6.1Disputes. Â Any dispute, controversy or claim arising from or related to this Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination hereof (a â€œDisputeâ€) that is not an Excluded Claim (as defined below) shall be finally resolved in accordance with Section 12.6.2. Â Notwithstanding the foregoing, any decisions that are subject to mutual agreement of the Parties will not be subject to the provisions of this Section 12.6 so long as such decisions are made in accordance with this Agreement.12.6.2Early Resolution; Arbitration.(a)Early Resolution. Â Any Dispute shall first be referred to the Executive Officers of the Parties, who shall confer in good faith on the resolution of the issue. Â Any final decision mutually agreed to by the Executive Officers shall be set forth in writing and shall be conclusive and binding on the Parties. Â If the Executive Officers are not able to agree on the resolution of any such Dispute within [*] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then the Parties shall submit such Dispute to be finally resolved by arbitration in accordance with Section 12.6.2(b). Â To the extent any Dispute relates to an action or decision required to be taken or made under the UPenn Agreement within a certain time period, the Parties shall use their best efforts to resolve such Dispute within such time period required for such action or decision. To the extent any such Dispute has not been resolved with such time period, and notwithstanding anything herein to the contrary, Passage shall have final decision making authority with respect to, and nothing herein shall prevent Passage from taking or making, any such action or decision required to be taken or made under the UPenn Agreement within such time period.(b)Arbitration. Â Any arbitration will be administered by the American Arbitration Association (â€œAAAâ€) in accordance with the AAAâ€™s Commercial Arbitration Rules in effect at the time of submission, as modified by this Section 12.6.2(b). Â The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the biopharmaceutical industry, each of whom will be impartial and independent. Â Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [*] following appointment of the second arbitrator, by the AAA. Â Such arbitration will take place in Philadelphia, Pennsylvania and will be conducted in English. Â The arbitration award will be a final and binding determination of the Dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 10.5. Â Subject to any award by the arbitration panel, each Party shall be responsible for its fees, costs, and expenses for conducting the arbitration; provided that the Parties will share payment for the third arbitrator.44â€‹â€‹12.6.3Confidentiality. Â Except to the extent necessary to comply with Law, legal process or a court order, or to enforce a final settlement agreement or secure enforcement of any arbitration award, the Parties agree that the existence, terms and content of any arbitration pursuant to Section 12.6.2(b), all information and documents disclosed in any such arbitration or evidencing any such arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any such arbitration, shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.12.6.4Excluded Claims. Â As used in this Section 12.6, the term â€œExcluded Claimâ€ means a dispute, controversy or claim that concerns (a) the validity or infringement of a Patent Right, trademark, copyright, or trade secret, or (b) any antitrust-, anti-monopoly- or competition-related Law. Â Any action concerning Excluded Claims may be brought in any court having jurisdiction.12.6.5Equitable Relief. Â Nothing in this Section 12.6 shall preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief, either prior to or during any arbitration, to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.12.7Waivers and Amendments. Â The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Â Any waivers under this Agreement must be in writing to be effective. Â No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.12.8Relationship of the Parties. Â The Parties have the relationship of independent contractors to each other under this Agreement, and nothing contained herein is intended or is to be construed so as to constitute one Party as a partner, agent, or joint venturer of the other Party. Â In addition, nothing in this Agreement shall be construed to give a Party the power or authority to act for, bind or commit the other Party or its Affiliates to or under any contract, agreement, or undertaking with any Third Party.12.9Notices. Â All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file) and sent as an attachment to an e-mail message, or (b) the earlier of when received by the addressee or [*] after the date it was sent, if sent by registered mail or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses or e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):If to Passage: Passage Bio, Inc.2005 Market St39th Floorâ€‹45â€‹â€‹Philadelphia, PA 19103ATTN: Chief Executive Officerâ€‹With a copy to (which shall not constitute notice):Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: General Counselâ€‹If to Gemma:Gemma Biotherapeutics, Inc.1831 Delancey PlacePhiladelphia, PA 19103ATTN: Chief Executive Officerâ€‹With a copy to (which shall not constitute notice): McDermott Will & Emery LLP200 Clarendon Street, Floor 58Boston, MA 02116ATTN: Brian Bunnâ€‹â€‹12.10No Third Party Beneficiary Rights. Â This Agreement is not intended to and shall 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 this Agreement or any provision contained herein or contemplated hereby. Â Notwithstanding the foregoing, each of Passage and Gemma agree and acknowledge that Penn is an intended third party beneficiary, and is entitled to rely on, the representations, warranties and covenants of Gemma, and remedies, set forth herein as if an original party to this Agreement.12.11Further Assurances. Â Passage and Gemma hereby agree without the necessity of any further consideration to execute, acknowledge, and deliver any and all administrative documents and take any ministerial action as may be reasonably necessary to carry out the intent and purposes of this Agreement.12.12Entire Agreement. Â This Agreement, the UPenn Agreement, and the Transition Services Agreement, including all Exhibits and Schedules hereto and thereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter, including the

CDA.12.13Counterparts. Â This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. Â All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Â Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an â€œElectronic Deliveryâ€) shall be treated in all 46â€‹â€‹manners and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Â Neither Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity.12.14Expenses. Â Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and signing of this Agreement.12.15Construction. Â The Parties acknowledge and agree that (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, and (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement.12.16Interpretation. Â The captions and headings in this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Â Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits of or to this Agreement and references to this Agreement include all Exhibits and Schedules hereto. Â If any conflict exists between the main body of this Agreement and any Exhibit or Schedule hereto, the main body of this Agreement shall prevail. Â Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words â€œincludeâ€ or â€œincludingâ€ shall be construed as incorporating, also, â€œbut not limited toâ€ or â€œwithout limitation;â€ (b) the word â€œdayâ€ or â€œyearâ€ means a calendar day or year unless otherwise specified; (c) the words â€œhereof,â€ â€œherein,â€ â€œherebyâ€ and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (d) the words â€œshallâ€ and â€œwillâ€ have interchangeable meanings for purposes of this Agreement; (e) the word â€œorâ€ shall have the inclusive meaning commonly associated with â€œand/orâ€; (f) words of any gender include the other genders; (g) words using the singular or plural number also include the plural or singular number, respectively; and (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.12.17Cumulative Remedies. Â No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, and each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.12.18Export. Â This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries which may be imposed upon or related to Gemma or Passage from time to time. Â Each Party agrees that it will not export, directly or indirectly, any 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 Body approval, without first obtaining the written consent to do so from the appropriate Governmental Body.
[Signature page follows]â€‹47â€‹â€‹IN WITNESS WHEREOF, the Parties intending to be legally bound have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.â€‹Passage Bio, Inc.Gemma Biotherapeutics, Inc.â€‹â€‹By: _/s/ Will Chou_____â€‹By: _/s/ Annalisa Jenkins_____Name: Will Chou, M.D.â€‹Name: Annalisa JenkinsTitle: Chief Executive OfficerTitle: Presidentâ€‹â€‹â€‹List of Schedules:â€‹Schedule 1.62: Licensed CompoundSchedule 1.121: UPenn Patents (existing as of the Effective Date)â€‹List of Exhibits:â€‹Exhibit A: Specified ObligationsExhibit B: Form of SDR ReportExhibit C: Form of Financial ReportExhibit D: Third Party MilestonesExhibit E: Diligence Eventsâ€‹[Signature Page to Exclusive License Agreement (MLD)]â€‹SCHEDULE 1.62LICENSED COMPOUNDâ€‹[*]â€‹â€‹â€‹â€‹SCHEDULE 1.121UPENN PATENTSâ€‹[*]â€‹â€‹â€‹â€‹EXHIBIT ASPECIFIED OBLIGATIONSâ€‹[*]â€‹â€‹EXHIBIT BFORM OF SDR REPORTâ€‹[*]â€‹â€‹â€‹â€‹EXHIBIT CFORM OF FINANCIAL REPORTâ€‹[*]â€‹â€‹â€‹â€‹EXHIBIT DTHIRD PARTY MILESTONESâ€‹[*]â€‹â€‹â€‹â€‹EXHIBIT EDILIGENCE EVENTSâ€‹[*]â€‹ â€œExhibit 10.4â€‹â€‹CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT PASSAGE BIO, INC. TREATS AS PRIVATE OR CONFIDENTIAL.â€‹â€‹TRANSITION SERVICES AGREEMENTThis Transition Services Agreement (this â€œAgreementâ€) is entered into as of July 31, 2024 (the â€œEffective Dateâ€), by and between Passage Bio, Inc., a corporation organized under the laws of Delaware (â€œPassageâ€) with offices at 2005 Market St, 39th Floor, Philadelphia, PA 19103, and Gemma Biotherapeutics, Inc., a Delaware corporation (â€œGemmaâ€) with offices at 1831 Delancey Place, Philadelphia, PA 19103. Â Passage and Gemma may be referred to in this Agreement individually as a â€œPartyâ€ or collectively as the â€œParties.â€ Capitalized terms used but not defined herein will have the meanings ascribed to them in the applicable License Agreement (as defined below).RECITALSWHEREAS, Passage owns and controls a drug development program for the treatment of GM1 gangliosidosis (the â€œGM1 Programâ€), pursuant to which it is currently conducting a study of safety, tolerability and efficacy of PBGM01 in pediatric participants with GM1 gangliosidosis (Imagine-1) (the â€œGM1 Studyâ€);WHEREAS, Passage additionally owns and controls drug development programs for the treatment of Krabbe disease (the â€œKrabbe Programâ€) and metachromatic leukodystrophy (the â€œMLD Program,â€ and together with the GM1 Program and Krabbe Program, the â€œProgramsâ€), pursuant to which it manages the clinical supply for the Programs (the â€œClinical Supplyâ€);WHEREAS, the Parties have entered into those certain Exclusive License Agreements dated as of the Effective Date (each a â€œLicense Agreementâ€) pursuant to which Passage agreed to license to Gemma certain intellectual property rights owned or controlled by Passage to develop, manufacture and commercialize certain Licensed Products related to the Programs; andWHEREAS, in connection with the License Agreements, Gemma wishes to obtain from Passage and Passage wishes to provide to Gemma certain Services (as defined below) pursuant to the terms and conditions set forth in this Agreement.NOW, THEREFORE, in consideration of the foregoing and the mutual covenants, conditions, and provisions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:Article 1â€‹SERVICES1.1Scope of Services. Â Subject to the terms and conditions of this Agreement, Passage will use Commercially Reasonable Efforts to provide or cause its affiliates to use Commercially Reasonable Efforts to provide the Services set forth on Exhibit A hereto (each, a â€œServiceâ€ and 1â€‹â€‹collectively, the â€œServicesâ€). Â The Parties acknowledge the transitional nature of the Services and Gemma agrees to use Commercially Reasonable Efforts to transition each Service to its own internal organization or to obtain alternate third-party sources to provide the Services as promptly as practicable following the execution of this Agreement. Â This Agreement imposes no obligation on Passage to perform any services other than the Services set forth on Exhibit A. Â The provision of the Services by Passage hereunder shall be subject in all cases to Gemma fulfilling its obligations under this Agreement and providing sufficient information, resources (including funding), and access as reasonably necessary for Passage to satisfy its obligations under this Agreement. Â For the purposes of this Agreement, â€œCommercially Reasonable Effortsâ€ shall mean [*]. Â The Parties will use reasonable efforts to cooperate with each other in matters relating to the provision and receipt of the Services; provided [*].1.2Personnel. Â Passage shall have sole discretion and authority with respect to designating, employing, assigning, compensating and discharging personnel, third party service providers, subcontractors and consultants in connection with Passageâ€™s performance of the Services. Notwithstanding anything to the contrary herein and for clarity, (i) in no event shall Passage be obligated under this Agreement to retain or hire any specific personnel, third party service providers, subcontractors or consultants, acquire any equipment or technology, expand or modify any facilities, or incur any capital expenditures, unless Passage agrees in writing, in its sole discretion, to do so, and Gemma agrees to bear all related costs and expenses in accordance with the terms hereof, and (ii) in no event shall Passage or its Affiliates have any obligation to favor operation of Gemma or its Affiliates over Passageâ€™s own business operations or those of its Affiliates.1.3Interpretation. Â Gemma acknowledges that Passage is not in the business of providing services like the Services on a commercial armâ€™s-length basis to independent third parties and that this Agreement is only required on a temporary basis in order to facilitate the transition of the Programs from Passage to Gemma. Â The provisions of this Agreement will be interpreted in that context.Article 2â€‹TRANSFER OF MATERIALS/TRANSITION2.1Transition Plan. Â Within [*] after the Effective Date, the Parties shall finalize and mutually agree upon a transition plan, based on the draft attached hereto as Exhibit B, which shall set forth the activities to be undertaken by the Parties or their designees in order to facilitate the transition of the Programs from Passage to Gemma (the â€œTransition Planâ€). Â Once the Transition Plan is agreed upon, each Party shall use Commercially Reasonable Efforts to perform its activities under the Transition Plan.2.2Regulatory Materials. Â On a Licensed Product-by-Licensed Product basis, following the occurrence of the various milestones set forth in Exhibit C hereto (collectively, the â€œRegulatory Transfer Milestoneâ€), Passage shall and does hereby assign to Gemma all Regulatory Materials and Regulatory Submissions Controlled by Passage as of the Effective Date specific to such Licensed Product and set forth in Exhibit C hereto. Â Following the occurrence of the Regulatory Transfer Milestone, Passage will promptly commence the legal transfer of the IND(s) and clinical trial application(s) (â€œCTAsâ€; and each such application, individually, a 2â€‹â€‹â€œCTAâ€) related to such Licensed Product triggering a transfer of sponsorship as set forth in Exhibit C.2.3Manufacturing Agreement. Â Gemma shall notify Passage within [*] after the Effective Date whether Gemma wishes to continue to receive manufacturing services for the GM1 Program similar to those currently being provided or that are expected to be provided under Passageâ€™s existing agreement with Catalent Pharma Solutions (â€œCatalentâ€). Â Upon Passageâ€™s receipt of such request, Passage will use good faith efforts to facilitate an introduction with Catalent for the purpose of having Catalent begin providing such services to Gemma under a separate agreement.2.4Existing Product. Â The existing supply of the Licensed Products (the â€œExisting Productâ€) will be transferred to Gemma or its designee at Gemmaâ€™s sole cost and expense in the manner and quantities set forth in Exhibit D hereto. Â All Existing Product shall be provided on an â€œAS ISâ€ basis, without warranty of any kind, and Passage shall in no circumstance be obliged to replace any Existing Product. Â The Existing Product shall be delivered Incoterms EXW to Gemma or its designee at the facilities identified in Exhibit D hereto.2.5Assigned Contracts. On a contract-by-contract basis and pursuant to the requirements and timing set forth in the Transition Plan, Passage and Gemma will execute an assignment and assumption agreement agreed to by the Parties for the contracts listed in Exhibit E hereto (the date of such assignment for the applicable contract, the â€œAssignment Dateâ€, and all such contracts to be assigned under Exhibit E hereto, collectively, the â€œAssigned Contractsâ€). Â If requested by Passage, Gemma will enter into one or more novation agreements with Passage with respect to the Assigned Contracts. Â If any assignment pursuant to this Section 2.5 requires Third Party consent, Passage will use [*] to obtain such consent; provided [*].2.6Enrollment Commencement Milestones. Â Gemma shall not [*] until achievement of the requirements set forth in Exhibit F hereto (collectively, the â€œEnrollment Commencement Milestoneâ€).Article 3â€‹COOPERATION3.1Cooperation. Â The Parties will use reasonable efforts to cooperate with each other in all matters relating to Passageâ€™s performance and Gemmaâ€™s receipt of the Services, including the transfer of materials and regulatory authorizations. Â Subject to the terms and conditions set forth herein, Passageâ€™s information security, access, nondisclosure and confidentiality, and other reasonable policies and requirements, such cooperation will include exchanging information, and providing necessary access to relevant people, equipment, and systems, and cooperating with respect to obtaining and providing all consents, licenses, sublicenses, approvals, or rights reasonably necessary to permit each Party to perform its obligations hereunder.3.2Administration. Â The Partiesâ€™ respective Alliance Managers shall serve as the main point of contact for each Party for purposes of this Agreement.3.3Access and Confidentiality. Â While accessing any data processing or communications services or facilities of the other Party, each Party will, and will cause its 3â€‹â€‹Affiliates and subcontractors to, comply in all material respects with the other Partyâ€™s corporate information and physical security policies (including policies with respect to protection of proprietary information and other policies regarding the use of computing resources) as in effect from time to time and provided to that Party in writing. Â Gemma will not attempt to gain access to or use any information or systems of Passage and its Affiliates except as expressly authorized by Passage. Â The Parties acknowledge that the use and disclosure of each Partyâ€™s confidential information under this Agreement will be governed by the confidentiality terms of the License Agreement. Â If reasonably requested by Passage based on the nature of the Services, Gemma will enter into a data processing addendum with Passage prior to the performance of the applicable Services. Â For clarity, the confidentiality terms of this Agreement supersede the terms of that certain Mutual Confidentiality Agreement between the Parties effective as of December 1, 2022 with respect to any Confidential Information disclosed hereunder.Article 4â€‹FEES AND PAYMENT4.1Fees. Â As consideration for providing the Services, Gemma will pay to Passage the amount set forth on Exhibit A for the Services (collectively, â€œFeesâ€) in accordance with the invoicing procedures set out in Section 4.4. Â The Fees include (i) [*], and (ii) [*], in providing the Services as set forth on Exhibit A.4.2Out of Pocket Costs. Â The Fees owed hereunder shall include all out-of-pocket expenses Passage or any of its Affiliates actually incurs in connection with the performance of the Services or any other activities or as part of fulfilling any other obligations set forth on Exhibit A or as otherwise requested in writing by Gemma, as well as any license fees or other payments to third party vendors and services providers required to be paid by Passage or any of its Affiliates in connection with the performance of the Services (collectively, â€œOut-of-Pocket Costsâ€).4.3Pre-Effective Date Costs. Â Within [*] after the Effective Date, Gemma shall pay Passage an amount equal to the aggregate Fees actually incurred by Passage or any of its Affiliates on or after March 1, 2024 but prior to the Effective Date for any and all activities that would have comprised Services hereunder had such activities been performed during the Term (such amount, the â€œPre-Effective Date Costsâ€).4.4Payment. Â All Fees (other than Pre-Effective Date Costs, which shall be paid within [*] after the Effective Date) [*]. Â All payments hereunder will be paid in U.S. Dollars and made by wire transfer of immediately available funds to a bank account specified by Passage. Â All Fees and Pre-Effective Date Costs owed under this Agreement and not paid when due will accrue late charges at the rate of [*], or the highest rate permitted by any applicable laws, statutes, rules, regulations, ordinances, or other pronouncements having the binding effect of law of any governmental entity (collectively â€œLawâ€), whichever is lower. Â The Parties agree to promptly discuss any fee disputes in good faith. Â In the event of a default in payment of any payment owing under the terms of this Agreement, if it becomes necessary for Passage to undertake legal action to collect said payment, Gemma shall [*].4.5Taxes. Â Except as otherwise noted on the relevant invoice, the Fees do not include any taxes. Â Gemma will be responsible for and pay any and all federal, state, or local sales, use, 4â€‹â€‹value-added, goods and services and similar taxes, duties, charges, or levies (and any related interest and penalties) imposed on, or in connection with the provision of the Services hereunder, but excluding any taxes measured by or imposed on Passageâ€™s net income. Â All payments made by or on behalf of Gemma under this Agreement shall be made without deduction or withholding for any taxes, unless Gemma is required to deduct or withhold such taxes under Law. Â If Gemma is required by any Law or regulation to withhold any amount for taxes from any payment due to Passage under this Agreement, then Gemma shall (i) make such withholdings as are required by Law, (ii) timely pay the full amount deducted or withheld to the appropriate governmental entity, and (iii) pay such additional amounts to Passage as may be necessary so that the net amount received by Passage after such withholding will not be less than the amount Passage would have received if such amounts had not been paid. Â At Passageâ€™s request, Gemma shall provide Passage with reasonably satisfactory documentation evidencing the payment to the appropriate governmental entity of any amounts so withheld or deducted.4.6No Set-Off. Â Each Party hereby acknowledges and agrees that it has no right under this Agreement to set off, discount or otherwise reduce or refuse to pay any amounts owed to the other Party under this Agreement against any other amount owed to it by the other Party, whether under this Agreement, the License Agreements or otherwise.Article 5â€‹TERM AND TERMINATION5.1Term. Â Unless earlier terminated, this Agreement is effective beginning on the Effective Date and will remain in effect for a period of six (6) months (the â€œTermâ€).5.2Termination for Convenience. Â Gemma may terminate any or all Service(s), or portion thereof, upon [*] written notice to Passage; provided, however, that with respect to any termination pursuant to this Section 5.2, Gemma shall be responsible for the payment of any and all charges and fees owed to Passage under this Agreement for such Service(s) rendered prior to the later of (A) the effective date of termination of such Service(s) and (B) in the event that Passage is contractually or legally required to incur expenses related to such Service(s) beyond the effective date of termination, the date that Passage is no longer contractually or legally required to incur such expenses. Â Notwithstanding the foregoing, Gemma acknowledges that certain Services may be dependent upon the provision of other Services and the termination of one Service (in whole or in part) may not be possible without the termination or reduction of a number of other Services (in whole or in part) and, that in the event of such a termination or reduction, Passage may, upon written notice to Gemma, terminate or reduce any other Service that is dependent upon the Service that has been terminated by Gemma.5.3Termination by Passage. Â Passage may terminate any Service, or portion thereof, upon written notice to Gemma to the extent the applicable service provider or personnel performing such Service, or portion thereof, terminates their relationship with Passage, or otherwise becomes unavailable to perform such Service, or portion thereof.5.4Termination for Cause. Â Either Party may terminate this Agreement in the event that the other Party materially breaches this Agreement and such material breach remains uncured 5â€‹â€‹for [*] (or [*] with respect to any payment breach) following receipt of written notice of such breach by the non-breaching Party.5.5Termination for Insolvency. Â In the event that either Party hereto shall (i) file a petition in bankruptcy, (ii) become or be declared insolvent, or become the subject of any proceedings (not dismissed within [*]) related to its liquidation, insolvency or the appointment of a receiver, (iii) make an assignment on behalf of all or substantially all of its creditors, or (iv) take any corporate action for its

winding up or dissolution, then the other Party shall have the right to terminate this Agreement by providing written notice to such Party.5.6Partial Termination. Â In the event of any termination or expiration with respect to one or more of the Service(s), but not all of the Service(s), this Agreement will continue in full force and effect with respect to any Service(s) not terminated or expired in accordance with this Agreement. Â Upon termination or expiration of this Agreement, or upon the termination or expiration of all of the Services in accordance with this Article 2, Passage will cease to perform the Services, and Gemma will pay to Passage all sums due to Passage pursuant to this Agreement for the Services. Â Termination of this Agreement or termination or expiration of any Service in accordance with this Article 2 will not relieve either Party from its obligations or liabilities arising hereunder prior to the date of such termination or expiration, nor will it affect the rights of either Party with respect to any claims or damages it may have suffered as a result of any breach of this Agreement by the other Party.5.7Effect of Termination. Â Article 2, Article 8, and Article 9, and Sections 3.3, 5.7 and 7.1 will survive any expiration or termination of this Agreement.Article 6â€‹COMPLIANCE6.1Legal Restrictions and Contractual Restrictions. Â Each Party will comply in all material respects with all Laws that govern the conduct of its own business operations with respect to the performance of its obligations under this Agreement. Â Notwithstanding anything to the contrary in this Agreement, Passage will not be obligated to provide a Service that, in Passageâ€™s reasonable discretion: (i) would be unlawful for Passage to provide under any Law; (ii) would breach the terms of any existing agreement between Passage and any third party or that would otherwise require the consent or similar approval of a third party, (iii) would require the extension or amendment of any existing agreement between Passage and any third party or, in the event of the termination of any existing agreement, entry into a new agreement between Passage and any third party, or (iv) would cause, or could reasonably be anticipated to cause, an adverse effect on Passageâ€™s business. Â If Passage is unable to provide a Service due to the limitations described in this Section 6.1, the Parties will discuss in good faith a substitute means of obtaining such Service, or obtaining replacement or substitute agreements that would permit either Passage to provide or Gemma to receive (whether independently or through a Third Party) such Service, in each case at Gemmaâ€™s sole cost and expense.6.2No Regulatory Advice. Â Passage is not responsible for ensuring Gemmaâ€™s regulatory and legal compliance under Law and the Parties agree that the Services are not a 6â€‹substitute for Gemmaâ€™s performance of any such compliance obligation or the engagement of appropriate advisors to assist with any such compliance obligation.Article 7â€‹INTELLECTUAL PROPERTY7.1No Transfer. Â Subject to Article 2 and Section 7.2, this Agreement and the performance of the Services hereunder will not affect, or result in the transfer of, any rights in or to, or the ownership of, any Know-How, Patent Rights, Regulatory Materials, Materials or other intellectual property rights of either Party. Â Neither Party will gain any rights of ownership with respect to any Know-How, Patent Rights, Regulatory Materials, Materials or other intellectual property rights or other property owned by the other Party by virtue of this Agreement or the provision of the Services hereunder, by implication, estoppel or otherwise.7.2Short-Term License. Â Gemma, on behalf of itself and its Affiliates, hereby grants to Passage (and solely for Passage to provide the Services, grants to Passageâ€™s subcontractors) for and during the Term, a non-exclusive, worldwide, non-transferable, fully paid-up, royalty-free license under all Know-How, Patent Rights, Regulatory Materials, Materials, and other intellectual property rights owned or controlled by Gemma or any of its Affiliates, solely for Passage (or such subcontractors) to perform the Services.Article 8â€‹INDEMNIFICATION AND LIABILITY8.1Indemnification.8.1.1Indemnification by Gemma. Â Subject to the provisions of this Article 8, Gemma shall defend, indemnify and hold the Passage Indemnitees harmless from and against any and all Losses arising out of any Third Party Claim related to: (i) the provision (or use by any Gemma Indemnitees) of the Services; (ii) a material breach by Gemma of any covenant or agreement contained in this Agreement; or (iii) Gemmaâ€™s (or its Affiliatesâ€™ or (sub)licenseesâ€™) performance, activities or omissions under the Assigned Contracts on or following the applicable Assignment Date; except, in each case (i)-(iii), to the extent such Losses arise out of any conditions set forth in Section 8.1.2(i)-(iii) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 8.1.2.8.1.2Indemnification by Passage. Â Subject to the provisions of this Article 8, Passage shall defend, indemnify and hold the Gemma Indemnitees harmless from and against any and all Losses arising out of any Third Party Claim related to: (i) the gross negligence, fraud or willful misconduct of any Passage Indemnitees in connection with this Agreement (including the performance of the Services); (ii) a material breach by Passage of any covenant or agreement contained in this Agreement; or (iii) Passageâ€™s (or its Affiliatesâ€™ or (sub)licenseesâ€™) performance, activities or omissions under the Assigned Contracts prior to the applicable Assignment Date (except to the extent Passage is performing under any such Assigned Contracts on behalf of Gemma as part of the Services); except, in each case (i)-(iii), to the extent such Losses arise out of any conditions set forth in Section 8.1.1(i)-(iii) for which Gemma is obligated to indemnify any Passage Indemnitee under Section 8.1.1.7â€‹â€‹8.1.3Indemnification Procedures. Subject to the provisions of this Article 8, Section 10.3 of the applicable License Agreement shall govern, mutatis mutandis, claims for indemnification under this Article 8.8.2Disclaimer. Â THE SERVICES ARE PROVIDED BY PASSAGE â€œAS ISâ€ AND PASSAGE MAKES NO EXPRESS OR IMPLIED WARRANTIES OR GUARANTEES WITH RESPECT TO THE SERVICES. Â NO STATUTORY WARRANTY OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OR OTHERWISE WILL APPLY TO THE SERVICES.8.3Limitation of Liability. Â NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, PUNITIVE, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES, LOST PROFITS, OR COST OF PROCUREMENT OF SUBSTITUTE PERSONNEL, TECHNOLOGY OR SERVICES, IN EACH CASE, WHETHER OR NOT SUCH FIRST PARTY HAS BEEN ADVISED OF OR WAS AWARE OF THE POSSIBILITY OF SUCH DAMAGES UNLESS CAUSED BY THE GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD OF SUCH FIRST PARTY. Â In addition, EXCEPT FOR A PARTYâ€™S INDEMNIFICATION OBLIGATIONS HEREUNDER, BREACH OF CONFIDENTIALITY OBLIGATIONS HEREUNDER, GROSS NEGLIGENCE, INTENTIONAL MISCONDUCT OR FRAUD, in no event shall the collective, aggregate liability (including, but not limited to, contract, negligence and tort liability) of SUCH PARTY or its affiliates, or SUCH PARTYâ€™s or its affiliatesâ€™ directors, officers, employees, subcontractors and agents, under this Agreement exceed [*].Article 9â€‹GENERAL9.1Assignment. Â This Agreement may not be assigned or transferred by either Party in whole or in part without the prior written consent of the other Party. Â Notwithstanding the foregoing, either Party shall have the right, without the prior written consent of the other Party, to assign or transfer this Agreement or its rights and obligations hereunder to (i) an affiliate, or (ii) in connection with the transfer or sale of all or substantially all of such Partyâ€™s business to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise. Â A Party shall notify the other Party in writing of any assignment of this Agreement by such Party within [*] thereof. Â The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the applicable Party. Â Any attempted assignment not in accordance with this Section 9.1 shall be void. Â Any permitted assignee shall assume all assigned obligations of its assignor under this Agreement.9.2Severability. Â Should one or more of the provisions of this Agreement become void or unenforceable as a matter of Law, then this Agreement shall be construed as if such provision were not contained herein and the remainder of this Agreement shall be in full force and effect, and the Parties will use their best efforts to substitute for the invalid or unenforceable provision a valid and enforceable provision that conforms as nearly as possible with the original intent of the Parties.8â€‹â€‹9.3Governing Law; English Language. Â This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania, without reference to any rules of conflict of laws that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Â The United Nations Convention on Contracts for the International Sale of Goods (CISG) of 11 April 1980 shall not be applicable. Â This Agreement was prepared in the English language, which language shall govern the interpretation of, and any dispute regarding, the terms of this Agreement.9.4Dispute Resolution.9.4.1Disputes. Â Any dispute, controversy or claim arising from or related to this Agreement, including the formation, existence, validity, enforceability, performance, interpretation, breach, or termination hereof or thereof (a â€œDisputeâ€) that is not an Excluded Claim (as defined below) shall be finally resolved in accordance with Section 9.4.2. Â Notwithstanding the foregoing, any decisions that are subject to mutual agreement of the Parties will not be subject to the provisions of this Section 9.4 so long as such decisions are made in accordance with this Agreement.9.4.2Early Resolution; Arbitration.(a)Early Resolution. Â Any Dispute shall first be referred to the Chief Executive Officers of the Parties, or their designee(s), provided that any such designee must have decision-making authority on behalf of the applicable Party (each, an â€œExecutive Officerâ€), who shall confer in good faith on the resolution of the issue. Â Any final decision mutually agreed to by the Executive Officers shall be set forth in writing and shall be conclusive and binding on the Parties. Â If the Executive Officers are not able to agree on the resolution of any such Dispute within [*] (or such other period of time as mutually agreed by the Executive Officers) after such Dispute was first referred to them, then either Party shall submit such Dispute to be finally resolved by arbitration in accordance with Section 9.4.2(b). Â (b)Arbitration. Â Any arbitration will be administered by the American Arbitration Association (â€œAAAâ€) in accordance with the AAAâ€™s Commercial Arbitration Rules in effect at the time of submission, as modified by this Section 9.4.2(b). Â The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the biopharmaceutical industry, each of whom will be impartial and independent. Â Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within thirty (30) days following appointment of the second arbitrator, by the AAA. Â Such arbitration will take place in Philadelphia, Pennsylvania and will be conducted in English. Â The arbitration award will be a final and binding determination of the Dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Article 8. Â Subject to any award by the arbitration panel, each Party shall be responsible for its fees, costs, and expenses for conducting the arbitration; provided that the Parties will share payment for the third arbitrator. Â 9.4.3Confidentiality. Â Except to the extent necessary to comply with Law, legal process or a court order or to enforce a final settlement agreement or secure enforcement of any arbitration award, the Parties agree that the existence, terms and content of any arbitration pursuant 9â€‹â€‹to Section 9.4.2(b), all information and documents disclosed in any such arbitration or evidencing any such arbitration results, award, judgment or settlement, or the performance thereof, and any allegations, statements and admissions made or positions taken by either Party in any such arbitration, shall be treated and maintained in confidence and are not intended to be used or disclosed for any other purpose or in any other forum.9.4.4Excluded Claims. Â As used in this Section 9.4, the term â€œExcluded Claimâ€ means a dispute, controversy or claim that concerns (a) the validity or infringement of a patent, trademark, copyright, or trade secret, or (b) any antitrust-, anti-monopoly- or competition-related Law. Â Any action concerning Excluded Claims may be brought in any court having jurisdiction.Â 9.4.5Equitable Relief. Â Nothing in this Section 9.4 shall preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or other interim equitable relief, either prior to or during any arbitration, to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.9.5Excusable Non-performance. Â The obligations of Passage to provide Services will be suspended to the extent that Passage is prevented from providing such Services by: (i) any Law; (ii) any act or omission of Gemma; or (iii) any other cause beyond the reasonable control of Passage, including, but not limited to, acts of God, civil disturbances, acts of war or conditions arising out of or attributable to war (whether declared or undeclared), terrorism, rebellion, insurrection, riot, invasion, fire, storm, flood, earthquake, denial of service and other malicious attacks, power outages, strikes, lockouts, or other labor or industrial disputes. Â Without limiting Section 6.1, in such event of such suspension, Passage will give notice of such suspension to Gemma as soon as reasonably practicable, stating the date and extent of such suspension and the cause thereof and will use Commercially Reasonable Efforts to overcome such cause and resume the provision of such Services after the cessation of such cause if the Term has not expired. Â If Passage is excused from providing any Service in accordance with the terms of this paragraph, Gemmaâ€™s sole and exclusive remedy will be to acquire such Service from any substitute source, at Gemmaâ€™s sole expense.9.6Waivers and Amendments. Â The waiver by either Party of any right hereunder, or of any failure of the other Party to perform, or of any breach by the other Party, shall not be deemed a waiver of any other right hereunder or of any other breach by or failure of such other Party whether of a similar nature or otherwise. Â Any waivers under this Agreement must be in writing to be effective. Â No provision of this Agreement may be amended or modified other than by a written document signed by authorized representatives of each Party.9.7Relationship of the Parties. Â The Parties have the relationship of independent contractors to each other under this Agreement, and nothing contained herein is intended or is to be construed so as to constitute one Party as a partner, agent, or joint venturer of the other Party. Â In addition, nothing in this Agreement shall be construed to give a Party the power or authority to act for, bind or commit the other Party or its affiliates to or under any contract, agreement, or undertaking with any third party.10â€‹â€‹9.8Notices. Â All notices, consents or waivers under this Agreement shall be in writing and will be deemed to have been duly given when (a) scanned and converted into a portable document format file (i.e., pdf file) and sent as an attachment to an e-mail message, or (b) the earlier of when received by the addressee or five (5) days after the date it was sent, if sent by registered mail or overnight courier by an internationally recognized overnight delivery service (receipt requested), in each case to the appropriate addresses or e-mail addresses set forth below (or to such other addresses and e-mail addresses as a Party may designate by notice):If to Passage: Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: Chief Executive Officerâ€‹With a copy to (which shall not constitute notice) to:Passage Bio, Inc.2005 Market St39th FloorPhiladelphia, PA 19103ATTN: General Counselâ€‹If to Gemma:1831 Delancey PlacePhiladelphia, PA 19103Attention:Â Chief Executive Officerâ€‹With a copy to (which shall not constitute notice) to: McDermott Will & Emery LLP200 Clarendon St. 57th FloorBoston, MA 02116Attention:Â Brian M. Bunnâ€‹9.9Entire Agreement. Â This Agreement, including all Exhibits hereto, sets forth the entire agreement and understanding of the Parties as to the subject matter hereof, and supersedes all proposals, oral or written, and all other communications between the Parties with respect to such subject matter.9.10Counterparts. Â This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. Â All such counterparts shall be deemed an original, shall be construed together, and shall constitute one and the same instrument. Â Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an â€œElectronic Deliveryâ€) shall be treated in all manners and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. Â Neither Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic 11â€‹â€‹Delivery as a defense to the formation of a contract, and each Party forever waives any such defense, except to the extent that such defense relates to lack of authenticity. 9.11Expenses. Â Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and signing of this Agreement.9.12Construction. Â The Parties hereto acknowledge and agree that (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision, and (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement. 9.13Interpretation. Â The captions and headings in this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Â Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits of or to this Agreement and references to this Agreement include all Exhibits hereto. Â If any conflict exists between the main body of this Agreement and any Exhibit hereto, the main body of this Agreement shall prevail. Â Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words â€œincludeâ€ or â€œincludingâ€ shall be construed as incorporating, also, â€œbut not limited toâ€ or â€œwithout limitation;â€ (b) the word â€œdayâ€ or â€œyearâ€ means a calendar day or year unless otherwise specified; (c) the words â€œhereof,â€ â€œherein,â€ â€œherebyâ€ and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (d) the words â€œshallâ€ and â€œwillâ€ have interchangeable meanings for purposes of this Agreement; (e) the word â€œorâ€ shall have the inclusive meaning commonly associated with â€œand/orâ€; (f) words of any gender include the other genders; (g) words using the singular or plural number also include the plural or singular number, respectively; and (h) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof.9.14Cumulative Remedies. Â No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, and each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.9.15Subcontracting. Â Passage may use its affiliates and subcontractors in the provision of the Services as it deems appropriate, provided that each such subcontractor agrees in writing to be bound by confidentiality obligations at least as protective as the terms of this Agreement and provided further that Passage remains responsible for the performance of each such affiliate and subcontractor and their compliance with the terms of this Agreement.9.16No Third-Party Beneficiaries. Â Unless otherwise expressly provided, no provisions of this Agreement are intended or will be construed to confer upon or give to any other person or entity, other than the Parties and their affiliates, successors and permitted assigns, any rights, remedies, or other benefits under or by reason of this Agreement. 9.17License Agreements. Â Neither the making nor the acceptance of this Agreement will enlarge, restrict, or otherwise modify the terms of the License Agreements or constitute a waiver or release by Gemma or Passage of any liabilities, obligations, or commitments imposed 12â€‹â€‹upon them by the terms of the License Agreements, including the representations, warranties, covenants, agreements, and other provisions set forth in the License Agreements. Â In the event of any conflict between the provisions of this

Agreement (including the exhibits hereto) and the provisions of a License Agreement, the provisions of the applicable License Agreement will control.9.18Priority. Â In the event any of the terms or conditions of the main body of this Agreement conflict with any of the terms or conditions of any Exhibit attached hereto, the terms or conditions of the main body of this Agreement will control and prevail over such terms or conditions of the Exhibit, as the case may be, but only to the extent of such conflict. â€‹â€‹[Remainder of Page Intentionally Left Blank]â€‹13â€‹â€‹â€‹IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorized representatives effective as of the Effective Date.â€‹Passage Bio, Inc.Gemma Biotherapeutics, Inc.â€‹â€‹By: _/s/ Will Chou_____â€‹By: _/s/ Annalisa Jenkins_____Name: Will Chou, M.D.â€‹Name: Annalisa JenkinsTitle: Chief Executive OfficerTitle: Presidentâ€‹[Signature Page to Transition Services Agreement]â€‹â€‹â€‹EXHIBIT A[*]â€‹â€‹â€‹â€‹â€‹â€‹â€‹EXHIBIT B[*]â€‹â€‹â€‹â€‹â€‹EXHIBIT C[*]â€‹â€‹â€‹â€‹â€‹EXHIBIT D[*]â€‹â€‹â€‹â€‹EXHIBIT E[*]â€‹â€‹â€‹â€‹â€‹EXHIBIT F[*]â€‹â€‹â€‹ â€‹Exhibit 10.5â€‹â€‹â€‹CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT PASSAGE BIO, INC. TREATS AS PRIVATE OR CONFIDENTIAL.â€‹â€‹RESEARCH, COLLABORATION & LICENSE AGREEMENTDATED AS OF July 31, 2024BY AND BETWEENGEMMA BIOTHERAPEUTICS, INC.ANDPASSAGE BIO, INC.â€‹â€‹ â€‹Câ€‹â€‹â€‹â€‹TABLE OF CONTENTSArticle 1 DEFINITIONSâ€‹2Article 2 COLLABORATION PROGRAMS; GOVERNANCEâ€‹122.1 Overall Projectâ€‹122.2 Researchâ€‹122.3 Funding of the Research Programs.â€‹142.4 Unavailability of Dr. James M. 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Gemma and Passage may be referred to herein as a â€œPartyâ€ or, collectively, as â€œPartiesâ€.RECITALS:WHEREAS, Passage and The Trustees of the University of Pennsylvania (â€œPennâ€) are parties to a Research, Collaboration & License Agreement, entered into on September 18, 2018, which was restated on May 5, 2020, and which was subsequently amended on August 13, 2020, November 2, 2020, December 9, 2020, June 2, 2021, August 3, 2021, November 12, 2021, December 3, 2021, May 11, 2022, and November 15, 2023 (collectively, as amended and restated, the â€œFirst ARCAâ€), pursuant to which Penn granted to Passage certain rights, licenses and options under certain Patent Rights (as defined below) and Know-How (as defined below) with respect to the research, development, manufacturing, and commercialization of certain products in certain indications;WHEREAS, concurrently with the execution of this Agreement, Penn and Gemma are entering into a business transaction under which the majority of the Wilson Laboratory (as defined below) resources will transition from Penn and into Gemma, and pursuant to which the Wilson Laboratory will no longer exist at Penn (such transaction, the â€œSpin-Out Transactionâ€);WHEREAS, concurrently with the execution of this Agreement, Passage and Penn are also entering into that certain Second Amended and Restated Research, Collaboration & License Agreement, effective as of the Effective Date (the â€œSecond ARCAâ€), pursuant to which Penn and Passage are amending and restating the First ARCA, including to account for the Spin-Out Transaction;WHEREAS, in connection with the Spin-Out Transaction and concurrently with the execution of this Agreement, Penn and Gemma are entering into that certain License Agreement (the â€œUpstream License Agreementâ€), pursuant to which Penn is granting to Gemma an exclusive license under certain Patent Rights and a non-exclusive license under certain manufacturing Patent Rights and Know-How;WHEREAS, Passage is a biopharmaceutical company with expertise in the development, manufacture and commercialization of human therapeutic products for the treatment of genetic disorders;WHEREAS, Gemma, through the Spin-Out Transaction, has technology and expertise in the research and development of gene therapy products; andWHEREAS, the programs contemplated by this Agreement are of mutual interest to Passage and Gemma and may benefit Passage and Gemma through the creation or discovery of new inventions and the development and commercialization of Licensed Products (as defined herein) for the Indications (as defined herein);NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:â€‹â€‹Article 1â€‹DEFINITIONSUnless otherwise specifically provided herein, the following terms shall have the following meanings:1.1.â€œAAVâ€ means adeno-associated virus.1.2.â€œAchievement Dateâ€ means with respect to a Diligence Event, the corresponding date such Diligence Event is to be achieved as provided in Section 5.7 below.1.3.â€œAffiliateâ€ means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.3, the word â€œcontrolâ€ (including, with correlative meaning, the terms â€œcontrolled byâ€ or â€œunder common control withâ€) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such Person, or by contract or otherwise.1.4.â€œBLAâ€ means (a) a biologics license application as that term is defined in the PHS Act and the regulations promulgated thereunder, (b) a marketing authorization application in the European Union, or (c) any equivalent or comparable application, registration or certification in any other country or region.1.5.â€œCalendar Quarterâ€ mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31 of each Calendar Year.1.6.â€œCalendar Yearâ€ means each successive period of twelve (12) months commencing on January 1 and ending on December 31.1.7.â€œcGLPâ€ means the current good laboratory practice regulations promulgated by the FDA, published at 21 U.S. C.F.R. Â§58, and equivalent non-United States regulations and standards in any other country or region, as applicable, as such current laboratory practices, regulations and standards may be amended from time to time.1.8.â€œcGMPâ€ means those current practices, as amended from time to time, related to the manufacture of pharmaceutical products and any precursors thereto promulgated in guidelines and regulations of standard compilations including the GMP Rules of the World Health Organization, the United States Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (established by the United States Department of Health and Human Services), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical products, and equivalent guidelines, regulations and standards in any other country or region, as such guidelines, regulations and standards may be amended from time to time.1.9.â€œChallengeâ€ means that Passage or a Sublicensee (including sub-Sublicensees) will be deemed to have made a â€œChallengeâ€ of the Licensed Patent Rights, Discovery Patent Rights, or a DRG Patent Right if Passage or such Sublicensee (including sub-Sublicensees), respectively: (a) institutes or voluntarily joins as a party to, or causes its counsel to institute on Passageâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, any interference, opposition, re-examination, post-grant review or similar proceeding with respect to any Licensed Patent Right, Discovery Patent Right, or a DRG Patent Right with the U.S. Patent and Trademark Office or any foreign patent office; or (b) 2â€Câ€‹â€‹makes any filing or institutes or voluntarily joins as a party to any legal proceeding, or causes its counsel to make any filing or institute or voluntarily join as a party to any legal proceeding on Passageâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, with a court or other Governmental Body (including, without limitation, the U.S. Patent and Trademark Office or any foreign patent office) having authority to determine the validity, enforceability or scope of the Licensed Patent Rights, Discovery Patent Rights, or a DRG Patent Right, in which one or more claims or allegations challenges the validity or enforceability of any Licensed Patent Right, Discovery Patent Right, or a DRG Patent Right.1.10.â€œClinical Studyâ€ means a Phase 1 Study, Phase 1/2 Study, Phase 2 Study, or Phase 3 Study, or such other study in humans that is conducted in accordance with good clinical practices and is designed to generate data in support or maintenance of an application for Regulatory Approval.1.11.â€œCNS Fieldâ€ means a disease or condition with significant morbidity in the central nervous system (â€œCNSâ€) or peripheral nervous system (â€œPNSâ€) [*]. For further clarity, [*]. 1.12.â€œCNS Indicationâ€ means an indication in the CNS Field.1.13.â€œCombination Productâ€ means a Licensed Product that is delivered with one or more additional active ingredients and/or other items or services incident to the administration of any such Licensed Product (with or without one or more such other active ingredients), [*], in each such case when any of the foregoing are co-formulated, co-packaged or sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).1.14.â€œCommercially Reasonable Effortsâ€ means the efforts and resources that a similarly situated biotechnology company would use for its own internally discovered technology of similar commercial potential and similar stage of development, taking into account the likely timing of the technologyâ€™s entry into the market and any patent and other proprietary position, safety and efficacy, product profile, and the then-current competitive and regulatory environments for the product. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party (a) promptly assign responsibility for such obligation to specific employee(s) who are accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.1.15.â€œCompulsory Licenseâ€ means a compulsory license under Licensed Patent Rights obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in any country. For clarity, [*].1.16.â€œControlledâ€ means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in this Agreement without (a) violating the terms of any other agreement or other arrangement with any Third Party from whom the Party or its Affiliate acquired such intellectual property rights, (b) requiring additional obligations, liabilities or financial consideration to such Third Party in connection with the grant of such license or sublicense (other than consideration for which Passage agrees to bear the entire cost), or (c) violating the terms of, or requiring additional obligations, liabilities or financial consideration to a Third Party under, [*].1.17.â€œDesignated Productâ€ means a Specified Licensed Product arising from a Research Program [*]. 3â€Câ€‹â€‹1.18.â€œDevelopment Transition Pointâ€ or â€œDTPâ€ means on a Licensed Product-by-Licensed Product basis, the date on which the IND-enabling studies for such Licensed Product under the applicable Research Program have been completed and immediately prior to filing of the IND, unless otherwise agreed by the Parties.1.19.â€œDiligence Eventâ€ means each of the events that Passage, itself or through any of its Affiliates or Sublicensees, is expected to accomplish in the development of each Licensed Product in each Indication set forth in Section 5.7. 1.20.â€œDiscovery Patent Rightsâ€ means [*].1.21.â€œDiscovery Programâ€ means the discovery research program conducted at Penn solely by the Wilson Laboratory during the period between January 1, 2016 and July 31, 2024 (inclusive), in the conduct of the discovery research program conducted at Penn prior to the Effective Date, which consisted of (a) [*], (b) [*], (c) [*], (d) [*]; (e) [*], and (f) [*].1.22.â€œDRG Excluded Indicationsâ€ means [*].1.23.â€œDRG Know-Howâ€ means all Know-How related to DRG Technology that is Controlled by Gemma and [*].1.24.â€œDRG Patent Rightsâ€ means (a) the Patent Rights [*], (b) [*], and (c) [*].1.25.â€œDRG Technologyâ€ means [*].1.26.â€œEMAâ€ means the European Medicines Agency and any successor entity thereto.1.27.â€œFD&C Actâ€ means the United States Federal Food, Drug and Cosmetic Act, as amended.1.28.â€œFDAâ€ means the United States Food and Drug Administration and any successor entity thereto.1.29.â€œField of Useâ€ means prophylactic, diagnostic and therapeutic uses in humans. For clarity, [*].1.30.â€œFIHâ€ means on a Licensed Product-by-Licensed Product basis, a first in human Clinical Study for a Licensed Product.1.31.â€œFirst Commercial Saleâ€ means, on a country-by-country basis, the first commercial transfer or disposition for value of Licensed Product in such country to a Third Party by Passage, or any of its Affiliates or Sublicensees, in each case, after Regulatory Approval has been obtained in and for such country.1.32.â€œFPFDâ€ means, on a Licensed Product-by-Licensed Product basis with respect to each Clinical Study, the first dosing of the first patient in such Clinical Study.1.33.â€œGAAPâ€ means United States generally accepted accounting principles applied on a consistent basis.1.34.â€œGene Therapy Productâ€ means a pharmaceutical product (or proposed or prospective pharmaceutical product) that inserts one or more functional genes or proteins into a patientâ€™s CNS or PNS cells using a parvovirus vector, including but not limited to an AAV. For clarity, Gene Therapy Products [*]. For clarity, [*]. 4â€Câ€‹â€‹1.35.â€œGeneric Productâ€ means, with respect to a particular Licensed Product in a country, a generic or biosimilar pharmaceutical product, that is not produced, licensed or owned by Passage, any of its Affiliates or Sublicensees, that: (a) is bioequivalent or biosimilar to such Licensed Product; and (b) is approved for use in such country by a Regulatory Authority by referencing the prior approval, in whole or part, or safety and efficacy data submitted in support of the prior approval, of the Licensed Product. Generic Product includes, but is not limited to, any pharmaceutical products for which Regulatory Approval is obtained via: (i) a bioequivalence or bioavailability showing such as those covered by section 505(j) of the FD&C Act or an equivalent outside the United States; or (ii) a biosimilarity or interchangeability determination such as those covered by section 351(k) of the PHS Act or an equivalent outside the United States.1.36.â€œGovernmental Bodyâ€ means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.1.37.â€œHD Research Programâ€ means the Transferred Research Program for HD. 1.38.â€œINDâ€ means an Investigational New Drug Application as defined in the FD&C Act and the regulations promulgated thereunder, or the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, including a Clinical Trial Authorization (â€œCTAâ€) to the European Medicines Agency, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.1.39.â€œIND Clearanceâ€ means on a Licensed Product-by-Licensed Product basis, the date on which the IND-enabling studies for such Licensed Product under the applicable Research Program have been completed, Passage has filed the IND with a Regulatory Authority, and such Regulatory Authority has cleared such IND as safe to proceed, unless otherwise agreed in writing by the Parties.1.40.â€œIndicationâ€ means each of the following indications for a Gene Therapy Product: (a) Huntingtonâ€™s disease (â€œHDâ€), (b) Temporal Lobe Epilepsy (â€œTLEâ€), and (c) parvovirus vector delivery of nucleic acid polymers for a specific disease indication within the CNS Field added to this Agreement through exercise of a New Indication Option (collectively, the â€œIndicationsâ€). 1.41.â€œKnow-Howâ€ means intellectual property, data, results, pre-clinical and clinical protocols and study data, chemical structures, chemical sequences, information, inventions, formulas, techniques, methods, processes, procedures, and developments. For clarity, â€œKnow-Howâ€ does not include Licensed Patent Rights, Discovery Patent Rights, or DRG Patent Rights claiming any of the foregoing. â€œKnow- Howâ€ also does not include Licensed Materials.1.42.â€œLawâ€ or â€œLawsâ€ means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.1.43.â€œLicensed Know-Howâ€ means all Know-How that is Controlled by Gemma that is necessary or reasonably useful to develop, make, use, sell, offer for sale or import a Licensed Product in the Field of Use, including, but not limited to, any such Know-How (a) licensed to Gemma pursuant 5â€Câ€‹â€‹to the Upstream License Agreement, or (b) developed or discovered under any of the Research Programs on behalf of Gemma (including but not limited to all Research Results generated by or on behalf of Gemma). 1.44.â€œLicensed Materialâ€ means biological or chemical materials that are Controlled by Gemma and necessary

or useful to exploit the licenses granted to Passage under this Agreement, to the extent that Gemma is (as of the Effective Date or at any relevant time during the Term thereafter) able to grant rights to such materials to Passage. Such biological and chemical materials include cell lines, viral seed stocks, product- specific reference materials, platform or product specific assay controls and reagents that are not available as standard commercial items. 1.45.â€œLicensed Patent Rightsâ€ means Licensed Patent Rights A and Licensed Patent Rights B, collectively.1.46.â€œLicensed Patent Rights Aâ€ means (a) the Patent Rights listed in Exhibit A, (b) [*], (c) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, and further including continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to the Research Program), (d) Gemmaâ€™s interest in and to any jointly owned Patent Rights of the kind described in Section 2.2.4, and (e) any corresponding foreign Patent Rights to the foregoing.1.47.â€œLicensed Patent Rights Bâ€ means: (a) [*]; (b) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, and further including continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to the Research Program); and (c) any corresponding foreign Patent Rights to the foregoing. Â For clarity, [*].1.48.â€œLicensed Productâ€ means any (a) process, service or method covered by a Valid Claim or whose use or practice would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim, or would infringe a Valid Claim once issued (â€œMethodâ€); (b) article, composition, apparatus, substance, chemical or any other material covered by a Valid Claim or whose manufacture, import, use, offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim or would infringe a Valid Claim once issued; (c) service, article, composition, apparatus, chemical, substance or any other material made, used or sold by or utilizing or practicing a Method, or (d) any product that incorporates or makes use or is made through use of Licensed Know-How, in each case (a) through (d), for an Indication. For clarity, [*].1.49.â€œMajor Marketsâ€ means the United States, Japan, France, Germany, Spain, Italy and the United Kingdom.1.50.â€œMHLWâ€ means the Ministry of Health, Labor and Welfare of Japan.1.51.â€œNet Salesâ€ means the gross consideration invoiced or received by Passage or any of its Affiliates or Sublicensees (including all sub-Sublicensees) for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary: 6â€Œâ€‹â€‹(a)trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds;(b)allowances or credits actually granted upon claims, returns or rejections of products;(c)charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the Sale, transportation, delivery or return of such Licensed Product; (d)customs duties, sales, excise and use taxes actually paid in connection with the transportation, distribution, use or Sale of such Licensed Product (but excluding what is commonly known as income taxes);(e)bad debt expense and amounts actually written off by reason of uncollectible debt not to exceed [*] of the Net Sales of Licensed Product.Even if there is overlap between any of the deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation.In the case of a Combination Product, the Parties shall negotiate in good faith, at the latest [*] before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, as the case may be, based on the fair market value of such components for the purposes of determining a product-specific allocation of such Net Sales. Payments related to such Combination Product under this Agreement, including Royalties and Milestone Payments, will be calculated, due and payable based only on the portion of such Net Sales so allocated to the Licensed Product components.In case of disagreement and failure by the Parties to agree upon an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, [*].1.52.â€œNext Generation Capsidâ€ means a specific parvovirus vector identified by sequence that is discovered, developed or engineered in the Discovery Program or by Gemma during the Term.1.53.â€œOptionâ€ means a New Indication Option and/or a Next Generation Indication Option, in each case as the context may require.1.54.â€œOption Periodâ€ means the period commencing on the Effective Date and expiring on the [*] anniversary thereof. Â 1.55.â€œPatent Rightsâ€ means (a) patents and patent applications, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part, reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions, including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing, and (b) all official correspondence relating to the foregoing.1.56.â€œPersonâ€ means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof. 7â€Œâ€‹â€‹1.57.â€œPhase 1 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. Â§312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. The drug candidate can be administered to patients as a single agent or in combination with other investigational or marketed agents.1.58.â€œPhase 1/2 Studyâ€ means a clinical study of a drug candidate in diseased human patients that satisfies the requirements of a Phase 1 Study and a Phase 2 Study.1.59.â€œPhase 2 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. Â§312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. Â§312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. Â§312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Clinical Study (e.g., a phase 1/2 trial). The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.60.â€œPhase 3 Studyâ€ means a clinical study of a drug candidate in human patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.61.â€œPHS Actâ€ means the United States Public Health Service Act, as amended.1.62.â€œProgram Budgetâ€ means a New Program Budget and/or a Next Generation Indication Program Budget, in each case as the context may require.1.63.â€œProgram Extension Research Termâ€ means, for any Indication for which the Research Plan agreed upon by the Parties for a Research Program remains in effect at the expiration of the Option Period, the period beginning upon the expiration of the Option Period until completion of such outstanding Research Plan for such Indication. 1.64.â€œRegulatory Approvalâ€ means, with respect to a product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use, marketing and sale of such pharmaceutical product in such jurisdiction in accordance with Laws. â€œRegulatory Approvalâ€ does not include authorization by a Regulatory Authority to conduct named patient, compassionate use or other similar activities.1.65.â€œRegulatory Authorityâ€ means any Governmental Body, including the FDA, EMA or MHLW, or any successor agency thereto, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical product in any country.1.66.â€œResearch Planâ€ means the research plan setting forth the Partiesâ€™ roles and responsibilities for each Research Program as set forth in Exhibit B hereto, respectively, and as may be amended from 8â€Œâ€‹â€‹time to time with written approval of the JSC or (to the extent provided herein) both Parties (collectively, all such Research Plans, the â€œResearch Plansâ€). 1.67.â€œResearch Programâ€ means the pre-clinical discovery, research, and/or development program of Licensed Products in the Field of Use for each of the Indications funded by Passage and to be conducted or continued to be conducted by the Parties hereunder (collectively, all such Research Programs, the â€œResearch Programsâ€). For clarity, [*]. 1.68.â€œResearch Resultsâ€ means all any and all ideas, information, inventions, developments, animate and inanimate materials, including live animals, discoveries, software, Know-How, methods, techniques, formulae, data, software, processes, methodologies, techniques, biological materials, software and works of authorship, whether patentable or copyrightable, that are first conceived, discovered, developed, reduced to practice, or generated in the performance of (a) the [*] or (b) prior to the Effective Date, by Penn through the Wilson Laboratory in performance of the [*], in each case (a) and (b), including any unpatentable inventions discovered, developed or conceived in the conduct of any of the Research Programs or Discovery Program. Research Results expressly excludes Licensed Patent Rights, Discovery Patent Rights, and DRG Patent Rights.1.69.â€œSaleâ€ means any transaction for which consideration is received or invoiced by Passage, its Affiliates or Sublicensees for sale, use, lease, transfer or other disposition of a Licensed Product to or for the benefit of a Third Party. For clarity, sale, use, lease, transfer or other disposition of a Licensed Product by Passage or any of its Affiliates or Sublicensees to another of these entities for resale (or other disposition) by such entity to a Third Party shall not be deemed a Sale.1.70.â€œService Center Coresâ€ means the following core laboratories at Penn that reported directly to Dr. James M. Wilson prior to the Effective Date: [*].1.71.â€œSpecified Licensed Productâ€ means a Licensed Product containing [*].1.72.â€œSpecified Obligationsâ€ means the licenses, options, and obligations that Gemma owes to a Third Party that are identified in Exhibit E, [*].1.73.â€œSublicense Documentsâ€ means any and all agreements, amendments or written understandings entered into with a Sublicensee (including any of its Affiliates) that are directly or indirectly related to a Sublicense, Licensed Patent Rights or Licensed Product. For clarity, a development agreement or distribution agreement for a Licensed Product is a Sublicense Document.1.74.â€œSublicenseeâ€ means a Person (including any Affiliate) to which a Sublicense is granted pursuant to the terms of Section 3.4.1.75.â€œSublicense Incomeâ€ means income received by Passage or its Affiliates in consideration for a Sublicense or for a grant of the right to negotiate or obtain a Sublicense, subject to the exclusions below. Sublicense Income includes such income received from a Sublicensee in the form of license issue fees, milestone payments and the like but specifically excludes (a) [*], (b) [*], (c) [*], (d) [*], or (e) [*].1.76.â€œTaxâ€ means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body. 9â€Œâ€‹â€‹1.77.â€œThird Partyâ€ means any Person other than Gemma, Passage or any of their respective Affiliates.1.78.â€œTLE Research Planâ€ means [*].1.79.â€œTLE Research Programâ€ means [*]. Â 1.80.â€œTransferred Research Programâ€ means [*]. 1.81.â€œUnited Statesâ€ or â€œUSâ€ means the United States of America, its territories and possessions.1.82.â€œUSDâ€ or â€œ$â€ means US dollars.1.83.â€œValid Claimâ€ means a claim of (a) an issued and unexpired patent in Licensed Patent Rights which claim has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no further appeal can be taken or has been taken within the time allowed for appeal, and has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer; or (b) a pending patent application (that has been pending for no more than [*] from the filing date of such application) that is included in Licensed Patent Rights which was filed and is being prosecuted in good faith, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.1.84.â€œWilson Laboratoryâ€ means Dr. James M. Wilson and all individuals [*].1.85.Other Terms. The definition of each of the following terms is set forth in the section of this Agreement indicated below:Defined TermSectionAdvance Payment6.2.2AgreementIntroductory ClauseAlliance Manager2.11.2Approved Subcontractor2.2.6Clinical Candidate Designation2.6.2(a)CNS1.11Commercial Milestone4.2.2(a)Commercial Milestone Payment4.2.2(a)Confidential Information7.1CTA1.38Default8.4.4Development Milestone4.2.1(a)Development Milestone Payment4.2.1(a)Disclosing Party7.1DP Review Period2.5.1(a)DRG1.25DRG Election Notice6.2.4DRG License3.1.2Effective DateIntroductory ClauseExclusive Licensed Patent Rights6.3.2Existing Research Plan2.5.1(a)Failed Indication2.10 10â€Œâ€‹â€‹Defined TermSectionFinancial Report4.6First ARCARecitalsGemmaIntroductory ClauseGemma Indemnitees9.1.1Gemma Sublicense Income4.4.1HD1.40Indemnified Party9.3.1Indemnified Party9.3.1Infringement Notice6.3.1Joint Steering Committee or JSC2.11.1(a)License3.1.1PassageIntroductory ClauseLicensing Exclusivity Period2.7Limited Collaboration Exclusivity Covenant2.8Losses9.1.1Maximum Anti-Stacking Reduction4.3.4(b)(iv)Method1.48New Indication2.5.2(a)New Indication Option2.5.2(a)New Indication Option Fee4.1.1New Program2.5.2(a)New Program Budget2.5.2(a)Next Generation Data Package2.5.1(a)Next Generation Indication Option2.5.1(a)Next Generation Indication Program2.5.1(a)Next Generation Indication Program Budget2.5.1(a)Next Generation Technology2.5.1(a)non-Publishing Party7.4Party or PartiesIntroductory ClausePassageIntroductory ClausePassage Indemnitees9.2.1Patent Costs6.2.1Patent Counsel6.1.1PennRecitalsPNS1.11Product Specific Patent Rights6.1.1Progress Report5.8.1Prosecution Request6.1.2Publishing Party7.4Receiving Party7.1Research Support Amount2.2.1Royalty4.3.1(a)Royalty Period4.3.2SDR Report3.4.4Second ARCARecitalsSpin-Out TransactionRecitalsSublicense3.4.1Term10.1 11â€Œâ€‹â€‹Defined TermSectionThird Party Claim9.1.1TLE1.27Upstream License AgreementRecitalsâ€‹Article 2â€‹COLLABORATION PROGRAMS; GOVERNANCE2.1Overall Project.The Parties desire to collaborate with respect to the pre-clinical development of Licensed Products, as set forth in more detail in this Article 2, in each Indication within the Field of Use, with the goal of identifying one or more Licensed Products for clinical development and commercialization in each Indication. As more specifically outlined herein, Gemma will be responsible, in consultation with Passage through the JSC, for certain preclinical development activities, including certain IND-enabling non-clinical studies and research grade manufacturing, and all activities set forth in the Research Plans (as applicable) that are not identified therein as Passageâ€™s responsibilities. Passage will be responsible for regulatory strategy and operations, clinical development, GMP manufacture, and commercialization of all Licensed Products. 2.2Research. 2.2.1During the period following the Effective Date until the completion or termination of the Research Plans, Passage shall provide an amount to be agreed upon based on the Research Plan for each Indication in research and development funding (â€œResearch Support Amountâ€) to Gemma to fund the Research Programs. The Research Support Amount is intended to fund Gemmaâ€™s discovery and pre-clinical research and development activities under the applicable Research Plan, including through IND-enabling studies for each of the named Indications (other than, subject to Section 2.2.2(b), TLE) as of the Effective Date. All such funding applicable to a particular Research Program shall be paid in advance of any work under such Research Program being conducted. As more specifically outlined in SectionÂ 2.3.1, Passage shall remit such funds, as applicable, during the Program Extension Research Term in accordance with a payment schedule and such funds will be allocated to Designated Product research and development programs as set forth in the applicable Research Plans and the Partiesâ€™ agreed-upon budget for each such Research Plan. Â 2.2.2Gemma will use commercially reasonable efforts to conduct the Research Programs in accordance with the respective Research Plans and the other terms and conditions of this Agreement. (a)Without limiting the foregoing, within each Indication, Gemma will be responsible, in consultation with Passage through the JSC, for the completion of the applicable Research Plan (subject to Section 2.2.2(b), with respect to the TLE Research Plan) for the agreed upon research and development work up to completion of IND-enabling studies, [*]. Gemma shall be responsible through the completion of the [*]. Passage shall be responsible for the clinical and commercial manufacture of the Designated Product in accordance with relevant cGMP.(b)The Parties acknowledge and agree that the TLE Research Program is paused as of the Effective Date until March 31, 2025, when the JSC will evaluate the TLE 12â€Œâ€‹â€‹Research Program and determine whether to resume or terminate the TLE Research Program. Â If the JSC determines to resume the TLE Research Program, the Parties will enter into an amendment to restart such TLE Research Program, and if the JSC determines to terminate the TLE Research Program, the Parties shall formally terminate such TLE Research Program. 2.2.3The JSC shall review the Research Plans at least once per Calendar Year. The JSC may amend the Research Plans at any time, including amendments to include further activities, including corresponding revisions to the budget.2.2.4Gemma shall maintain records of the results of the Research Programs in sufficient detail and in good scientific manner appropriate for patent purposes to properly reflect all work done and results achieved. Gemma will provide task-based, scientific reports of the progress and results of the Research Programs on the schedule specified in the respective Research Plans or on another schedule to be agreed in writing by the Parties. Upon Passageâ€™s reasonable request and at Passageâ€™s cost and expense, Gemma will disclose and deliver Research Results from the Research Programs to Passage, and will provide Passage with such additional information and technical assistance as may be reasonably needed for Passage to interpret and use such Research Results from the Research Programs. Gemma shall maintain records of the use of the funds provided by Passage and shall make such records available to Passage upon reasonable notice during Gemmaâ€™s normal business hours, but not more frequently than each anniversary of the Effective Date. As between the Parties, all Research Results shall be solely and exclusively owned by the Party that conceived and reduced to practice such Research Results, except to the extent (if any) that the Research Results from the Research Programs include any jointly invented patentable inventions for which a joint ownership interest vests in both Passage and Gemma or any of their respective personnel under default provisions of applicable U.S. patent Law. The Parties acknowledge that any such joint inventions will be subject to the provisions of Section 7.4 to the same extent as any other Research Results. In addition, unless otherwise agreed by the Parties in writing on a case-by-case basis, any Patent Rights corresponding to such joint inventions:

(a) will be jointly owned by the Parties; and (b) will be subject to this Agreementâ€™s royalty obligations and exclusivity terms, and also to the provisions of Article 6, [*].2.2.5The Parties hereby acknowledge that there are inherent uncertainties involved in the research and development of products and such uncertainties form part of the business risk involved in undertaking the Research Programs. Accordingly, in the event that upon completion of the Research Plan for a specific Indication (other than with respect to the TLE Research Plan prior to the amendment thereof, in accordance with Section 2.2.2(b)), the Parties do not develop or identify a suitable candidate to propose as a development candidate for that Indication, [*].2.2.6Each Party will have the right to engage Third Party subcontractors to perform certain of its obligations under this Agreement; provided that Gemmaâ€™s right to engage Third Party subcontractors is subject to Passageâ€™s prior written consent, which may not be unreasonably withheld, conditioned or delayed (each such subcontractor for which Passage has granted prior written consent, an â€œApproved Subcontractorâ€). Any subcontractor to be engaged by a Party to perform a Partyâ€™s obligations set forth in this Agreement must meet the qualifications typically required by such Party for the performance of work similar in scope and complexity to the subcontracted activity and will enter into such Partyâ€™s standard nondisclosure agreement consistent with such Partyâ€™s standard practices which 13â€Œâ€‹â€‹agreement shall be as least as protective as the nondisclosure obligations set forth herein. Any Party engaging a subcontractor hereunder will remain responsible and obligated for such activities and will not grant rights to such subcontractor that interfere with the rights of the other Party under this Agreement. Furthermore, if Gemma engages any subcontractor to perform any activities that would otherwise be performed by Gemma, [*].2.2.7Notwithstanding anything to the contrary, Passage may perform, at its sole expense, pre-IND activities contemplated under the HD Research Program (up to clinical candidate selection) outside of Gemma upon Gemmaâ€™s written consent.2.2.8With respect to the TLE Research Program and/or any future Research Program for which a Research Plan and budget therefor has already been agreed, including pursuant to the New Indication Option procedure set forth Section 2.5.2(a), Passage shall be required to obtain Gemmaâ€™s written consent prior to Passage commencing performance, at is sole expense, of any pre-IND activities (including IND-enabling studies) outside of Gemma for research activities that are part of such Research Program.2.2.9With respect to any other work (i.e., work that is not within the scope of work to be performed under Sections 2.2.7 or 2.2.8) that is proposed by Passage to be performed outside of Gemma, Passage shall be permitted to perform, at its sole expense, such work, provided such work and any data resulting therefrom is reviewed and discussed by the Parties at the JSC.2.3Funding of the Research Programs. 2.3.1Subject to Section 2.3.2, the budgets for each of the Research Programs shall be broken down by calendar month and by research and development activity to be performed (in the format agreed upon by the Parties), and will include: (a) [*]; (b) [*]; (c) [*]; and (d) [*]. Â The budgets for each of the Research Programs, as of the Effective Date, are set forth in Exhibit C. On or before [*] of each year, the Parties, through the JSC (subject to clause (b) of Section 2.3.2), will agree on an updated budget for the remainder of each of the Research Programs, also broken down by calendar month and by research and development activity. Subject to the terms and conditions of this Agreement, Passage shall pay Gemma research and development funding to cover the cost of the performance of the Research Plans by Gemma in accordance with the agreed-upon budget (as updated from time to time pursuant to this Agreement) and the terms of Section 4.5 (including reasonable and documented external expenses incurred by Passage in accordance with the Research Plans and as agreed to by the Parties through the JSC). The budget for each Research Plan shall be separated by calendar month and paid by Calendar Quarter in advance prior to the work to be performed for such Calendar Quarter in which such activities will take place.Calendar QuarterPercentage of Research Support Amount payable by Passage in a particular Calendar Yearâ€‹First Calendar Quarter[*]Second Calendar Quarter[*]Third Calendar Quarter[*]Fourth Calendar QuarterGemma will perform a full year-end reconciliation, and the Parties shall update the payment schedule for the budget for the following 14â€Œâ€‹â€‹Calendar QuarterPercentage of Research Support Amount payable by Passage in a particular Calendar Yearâ€‹Calendar Year of the Program Extension Research Term to account for any overpayment or underpayment in the then-current Calendar Year.â€‹â€‹2.3.2If at any time Gemma determines that it will require additional funds for any of the Research Programs, it will notify Passage through the JSC and provide a good faith estimate and itemized budget of the additional amount. Notwithstanding the foregoing: (a) changes to the scope of or budget for any of the Research Plans for a given Calendar Year will require approval of the JSC if the budget impact is greater than [*] of the agreed upon budget for such Research Plan for such Calendar Year; and (b) [*].2.3.3Unless otherwise indicated in the applicable Research Plan(s) or agreed-upon budget, title to any equipment, laboratory animals, or any other tangible materials made or acquired with funds provided under this Agreement will vest in Gemma, and such equipment, animals, or tangible materials will remain the property of Gemma following termination or expiration of this Agreement (but subject to any license grants to Passage hereunder).2.3.4Gemma shall maintain records of the use of the funds provided by Passage for performance of the Research Programs by Gemma and shall provide Passage with monthly financial reports, including copies of all invoices and any other supporting documentation related to any third-party contracted costs incurred during the applicable month, within [*] business days after the end of each [*].2.3.5Reconciliation of Research Programs Funding.2.3.5.1Â Reconciliation of Research Programs Funding. (a)Within [*] after the end of each Calendar Quarter during the Option Period and any Program Extension Research Term, Gemma will submit to Passage a reconciliation of all payments made by Passage and all expenses actually incurred by Gemma in the performance of each of the Research Programs for the previous Calendar Quarter. Subject to Section 2.3.5.1(b), the quarterly reconciliation and any adjustment of payment schedule will be the responsibility of a joint finance subcommittee formed by and under the authority of the JSC pursuant to Section 2.11.1(b), who will provide regular reports to the JSC.â€‹(b)Any overpayment by Passage shall be applied as a credit to the next quarterly payment owed by Passage. Any underpayment by Passage shall be added as an additional amount to the next quarterly payment owed by Passage, provided however that, on a month-by-month and research or development activity-by- research or development activity basis, Passage shall not be required to pay any amount that exceeds [*] of the amount budgeted for such research or development activity, without Passageâ€™s express written approval of such amount prior to the 15â€Œâ€‹â€‹incurrence thereof. If no further quarterly payments are owed with respect to a particular Research Program, (i) any underpayment shall be paid to Gemma within [*] after receipt by Passage of the final reconciliation report for such Research Program, or (ii) any overpayment shall be returned to Passage within [*] after receipt by Passage of such final reconciliation report; provided however that, on a month-by-month and research or development activity-by-research or development activity basis, Passage shall not be required to pay any amount that exceeds [*] of the amount budgeted for such research or development activity, without Passageâ€™s express written approval of such amount prior to the incurrence thereof.2.3.5.2Â Final Research Programs Reconciliation. Within [*] after the conclusion or early termination of all of the Research Programs (in their entirety), Gemma will submit to Passage a final reconciliation of all payments made by Passage and all expenses actually incurred by Gemma in the performance of each of the Research Programs as well as any non-cancellable costs and wind-down costs associated with each Research Program, respectively, in accordance with Section 10.4.4. Any (a) overpayment by Passage shall be refunded to Passage, and (b) underpayment by Passage shall be paid to Gemma, in each case (a) and (b), within [*] after the final reconciliation report is provided to Passage by Gemma, provided that, on a month-by-month and research or development activity-by-research or development activity basis, Passage shall not be required to pay any amount that exceeds [*] of the amount budgeted for such research or development activity, without Passageâ€™s express written approval of such amount prior to the incurrence thereof.2.4Unavailability of Dr. James M. WilsonIf, at any time during the Term, James M. Wilson, MD, PhD ceases to be affiliated with Gemma, then Passage shall have the right, exercisable in Passageâ€™s sole discretion by written notice to Gemma, to assume all of Gemmaâ€™s activities under the Research Programs in effect at such time. Â For clarity, [*]. Â 2.5Next Generation Indication Programs; New Programs.2.5.1Gemma Initiated Next Generation Indication Programs.(a)In the event that, during the Option Period, Gemma initiates a new Gene Therapy Product development program for an existing Indication (i.e., an Indication that at the time of such initiation is the subject of an ongoing or past Research Plan, also referred to as the â€œExisting Research Planâ€) and such initiation occurs prior to expiration of the Licensing Exclusivity Period for such existing Indication (â€œNext Generation Indication Programâ€), then Gemma will provide notice to Passage, in accordance with Section 11.11, of such Next Generation Indication Program. Following Passageâ€™s receipt of such notice, the Parties shall, as soon as reasonably practicable, have a preliminary discussion in good faith relating to the data package for such proposed Next Generation Indication Program. Â Following such preliminary discussion, Gemma shall provide Passage with a data package relating to such proposed Next Generation Indication Program, which shall include data relating to efficacy and safety for such Next Generation Indication Program (â€œNext Generation Data Packageâ€). If Passage has interest to include such Next Generation Indication Program in the License granted under this Agreement, Passage shall formally notify Gemma in writing within [*] days after Passageâ€™s 16â€Œâ€‹â€‹receipt of such Next Generation Data Package from Gemma (such period, the â€œDP Review Periodâ€) of its interest in such Next Generation Indication Program and Gemma will develop and propose within [*] days a work plan and budget for [*] subject to the reasonable review and approval by Passage (â€œNext Generation Indication Program Budgetâ€). Within [*] of Passageâ€™s receipt of the Next Generation Indication Program Budget and work plan, Passage shall decide whether to exercise its option to such Next Generation Indication Program (the â€œNext Generation Indication Optionâ€). The Parties acknowledge and agree that this Section 2.5.1(a) is intended to apply to research programs for [*] (â€œNext Generation Technologyâ€). Â For further clarity, [*]. (i)Exercise of any Next Generation Indication Option shall [*]. If Passage exercises a Next Generation Indication Option by written notice to Gemma, then (i) the Parties will amend the Research Program and Research Plan to include such Next Generation Indication Program, and (ii) the Research Support Amount will be increased by the amount of the Next Generation Indication Program Budget. Â For clarity, a Licensed Product arising from a Next Generation Indication Program shall be deemed a separate and distinct Licensed Product for such Indication under the terms of this Agreement and subject to all terms and conditions set forth in this Agreement, including but not limited to all diligence obligations and financial obligations for a separate Licensed Product.(ii)If (X) Passage fails to notify Gemma of its desire to exercise such Next Generation Indication Option for such Next Generation Indication Program in the time period set forth above in Section 2.5.1(a) and provide Gemma written notice of such exercise, or [*] within [*] after Passageâ€™s notice of its desire to exercise of such Next Generation Indication Option for such Next Generation Indication Program, and (Y) such Next Generation Indication Program [*], this Section 2.5.1(a) and Section 2.8 shall not apply, and Gemma may collaborate with, and license such Next Generation Indication Program to, a Third Party; provided, however, [*]. Â Further, Passage may not [*]. (iii)In the event that the Parties have a good faith scientific dispute over whether such Next Generation Indication Program has [*] to the existing Licensed Product for such Indication, then Passage shall provide written notice to Gemma during such DP Review Period for such Next Generation Indication Program. Â Upon receipt of such notification, the JSC shall meet and confer on such Next Generation Indication Program. Â In the event that the Parties cannot resolve such dispute at the JSC, then such dispute may be referred by either Party to a panel of [*]. Â Each Party [*], within [*] after their appointment. Â The panel of independent scientific experts can only determine whether such Next Generation Indication Program has [*] to the existing Licensed Product for such Indication. Â The determination of the panel shall not [*], and the determination made by such panel shall be final, binding and non-appealable on both Parties. Â No discovery other than an exchange of relevant documents may occur in the proceeding, and the Parties agree to act in good faith to promptly exchange the relevant documents. Â The cost of such panel and proceeding shall be borne equally by the Parties. The panel of experts chosen in accordance with these provisions will not have the power to alter, amend or otherwise affect the terms 17â€Œâ€‹â€‹of these arbitration provisions or any other provisions contained in this Agreement.2.5.2Passage Initiated Programs.(a)During the Option Period, if Passage wishes to include a new Gene Therapy Product development program for disorder in the CNS Field (each a â€œNew Indicationâ€) to be conducted by Gemma for a New Indication (â€œNew Programâ€), then Passage may formally make such request in writing to Gemma during the Option Period, as applicable. Promptly following Passageâ€™s delivery of such written request, the Parties shall discuss in good faith the details regarding such proposed New Program. Following such preliminary discussion in good faith, if the Parties mutually agree to proceed with such New Program, then Gemma will work with Passage to develop and propose within [*] a work plan and budget for the preclinical development costs through IND-enabling studies to be conducted at Gemma or Passage for such program, including any budget therefor (â€œNew Program Budgetâ€). Any such agreed budget will be added to the pre-existing Research Support Amount. Passage shall have [*] to negotiate and, if applicable, accept such work plan and budget and exercise its option to such New Program (the â€œNew Indication Optionâ€). If Passage exercises such New Indication Option, then within [*] after such option exercise, the definition of â€œIndicationâ€ (and the Research Program and Research Plan) will be amended to include the New Indication. Following Passageâ€™s exercise of such New Indication Option, Passage shall pay a New Indication Option Fee in accordance with Section 4.1.1. If the Parties are unable to agree on a new work plan and budget within such time period, [*].(b)If Passage wishes to include a Next Generation Indication Program for an Existing Research Plan or completed Research Plan for an Indication, then this Section 2.5.2(b) shall apply. Â The Parties acknowledge and agree that this Section 2.5.2(b) is intended to apply for the development of new Gene Therapy Products utilizing Next Generation Technology. Â For further clarity, [*].(i)Upon a proposal to Gemma by Passage of a Next Generation Indication Program, Passage shall have the right to include any Next Generation Indication Program in the License granted under this Agreement by exercising a Next Generation Indication Option in accordance with this Section 2.5. For clarity, [*]. Â Gemma shall have [*] right to conduct such development work pursuant to a new Research Program and Research Plan for such Next Generation Indication Program. Â For clarity, [*].(ii)If, despite good faith negotiations, the Parties fail to negotiate the work plan, Program Budget or specific gene replacement transgene within [*] after Passageâ€™s notice of its desire to exercise of such Next Generation Indication Option for such Next Generation Indication Program, Passage shall be free to conduct such development work for such Next Generation Indication Program.2.5.3Exercise and Termination of New Indication Options. Â The Parties acknowledge and agree that, beginning on the Effective Date, Passage shall have a total of four (4) New Indication Options under Section 2.5.2, which Passage may elect to exercise at any time until the expiration or termination of the Option Period. Upon the earlier of (i) exercise by 18â€Œâ€‹â€‹Passage of four (4) New Indication Options pursuant to Section 2.5.2, and (ii) expiration or termination of the Option Period, Gemma shall have no obligation under Section 2.5.2 to perform any additional New Program, or grant a license to any additional New Indication to Passage after such period. Â For clarity, [*]. Notwithstanding the foregoing, Passage may exercise a Next Generation Indication Option for a Next Generation Indication Program under Sections 2.5.1(a) or 2.5.2(b) [*].2.6Rights to Technologies arising from Discovery Program.2.6.1Generally. It is anticipated that Licensed Product development under the Research Programs will include the use of the most scientifically appropriate and available Next Generation Capsids and other technologies Controlled by Gemma (including, any such technologies arising from the Discovery Program prior to the Effective Date). As used throughout this Section 2.6, â€œavailableâ€ means that the Specified Obligations do not prevent the Next Generation Capsid from being offered or licensed to Passage as contemplated herein. For clarity, [*].2.6.2Ongoing Research Programs and Clinical Candidate Designation.(a)On an Indication-by-Indication basis and Licensed Product-by-Licensed Product basis (for clarity, whether or not the applicable Licensed Product arises from a Research Program), Passage shall provide written notification to Gemma upon the selection of [*] for a Licensed Product for such Indication. Passage may provide the foregoing notification with respect to a Licensed Product at or following Clinical Candidate Designation. â€œClinical Candidate Designationâ€ means [*]. Â (b)Upon Passageâ€™s delivery of a notification of a Specified Licensed Product under Section 2.6.2(a) on an Indication-by-Indication and Licensed Product-by-Licensed Product basis, a new Exhibit A-1 shall be created upon Gemmaâ€™s receipt of Passageâ€™s request, which request shall specify the Licensed Patent Rights A and Licensed Patent Rights B that cover the applicable Specified Licensed Product for the applicable Indication.2.6.3After IND Clearance. In the event that following IND Clearance for a Specified Licensed Product for an Indication, a Discovery Patent Right is useful or necessary for such Specified Licensed Product for such Indication, Exhibit A-1 shall be amended upon Gemmaâ€™s receipt of Passageâ€™s request, which request shall specify the additional Licensed Patent Rights B that cover the applicable Specified Licensed Product for such Indication. 2.7Licensing Exclusivity.Subject to Gemmaâ€™s retained rights in Section 3.2, Gemma shall not license, or grant any other rights in or to, any Licensed Patent Rights conceived and reduced to practice in the conduct of any Research Program [*] or any Discovery Patent Rights to another Third Party for an Indication that is the subject of a Research Program for a period of the greater of (a) [*] after Gemmaâ€™s initiation of work under the Research Program for such Indication and (b) [*] after IND Clearance for such Indication, (â€œLicensing Exclusivity Periodâ€) provided that Gemma Â conducts the Research Plan [*] for such product candidate for such Indication under this Agreement (further provided that the Licensing Exclusivity Period will apply if Gemma is unwilling or unable to perform [*], including through the use of a subcontractor, or has agreed to allow Passage to perform such studies as set forth in Section 2.2.7). At the conclusion of the Licensing Exclusivity Period, or earlier if the 19â€Œâ€‹â€‹Research Plan for such Indication has been terminated, Gemma shall have the right to license any [*] for the Indication [*]. For clarity, [*]. Notwithstanding the foregoing, the restriction and Licensing Exclusivity Period set forth in SectionÂ 2.7 shall not apply to a Next Generation Indication Program that is not included in the License as a result of the application of Section 2.5.1(a)(ii), and Gemma shall be free to license to a Third Party the Discovery Patent Rights for such Next Generation Indication Program [*]. 2.8Limited Collaboration Exclusivity.On an Indication-by-Indication basis during the Option Period or the Program Extension Research Term solely with respect to such Designated Product for an Indication subject to such Program Extension Research Term until the earlier of: (a) [*], or (b) [*], Gemma shall not collaborate with any Third Party to develop another Gene Therapy Product

for the same Indication (as that term is defined as of the Effective Date and as it may be updated during the Term when additional New Indications are included pursuant to the terms of this Agreement) (â€œLimited Collaboration Exclusivity Covenantâ€). Notwithstanding the foregoing, the Limited Collaboration Exclusivity Covenant shall end on an Indication-by-Indication and Licensed Product-by-Licensed Product basis upon the earlier of: (i) [*]; (ii) [*]; or (iii) [*]. Â For clarity, [*]. 2.9Non-Compete.During the Term, Gemma will not itself, or with or through any of its Affiliates or any Third Party, (a) either (i) directly or indirectly, conduct or participate in, or (ii) grant a license or covenant not to sue under intellectual property rights to any Third Parties for, in each case ((i) or (ii)), the research, development, commercialization, or other exploitation of any [*]. Â 2.10Program Failure.In the event that the Research Program associated with any Licensed Products for any particular Indication fails at a key decision point during the Research Program, as such failure is objectively defined in the work plan for such project, and a decision is subsequently made by Passage to discontinue further development of the program for such Indication (â€œFailed Indicationâ€), any remaining Research Support Amount allocated for the Failed Indication program (minus wind-down and non-cancellable expenses) will be refunded to Passage within [*] after Passageâ€™s delivery of written notice to Gemma of such decision to discontinue. Such Failed Indication will be removed promptly from the Indication definition of this Agreement, with written confirmation of such reversion of rights promptly provided by Passage to Gemma. In addition, any [*] shall terminate immediately with respect to any Failed Indication. Â 2.11Governance.2.11.1Joint Steering Committee.(a)Formation; Composition. The Parties shall establish a joint steering committee (the â€œJoint Steering Committeeâ€ or â€œJSCâ€) comprised of three (3) representatives from each Party with sufficient seniority within the applicable Party to make decisions arising within the scope of the JSCâ€™s responsibilities. The JSC may change its size from time to time by mutual consent of its members, provided that the JSC will consist at all times of an equal number of representatives of each of Gemma and Passage. Each Party may replace its JSC representatives at any time upon written notice to the other Party. 20â€Œâ€‹â€‹(b)Specific Responsibilities. The JSC will:(i)oversee each of the Research Programs; provided, however, that any post-DTP activities of Passage are outside the purview of the JSC except to the extent (if any) otherwise expressly agreed in the Research Plans (as applicable);(ii)on or before November 1 of each year, approve (once acceptable to the JSC) an updated budget in accordance with Section 2.3.1 and subject to clause (b) of Section 2.3.2;(iii)approve (once acceptable to the JSC) any amendments to the Research Plans (including any changes to the budget that are greater than [*] of the then-current budget for the then-current Calendar Year), subject to clause (b) of Section 2.3.2;(iv)[*];(v)review and (if acceptable) approve IND submissions and any other filing with a Regulatory Authority prior to IND submissions relating to a Licensed Product;(vi)use good-faith efforts to resolve any disagreement between the Parties relating to any of the Research Programs or Research Plans;(vii)use good faith efforts to resolve any disagreement between the Parties relating to a Next Generation Indication Program; (viii)establish such additional subcommittees as it deems necessary to achieve the objectives and intent of each of the Research Programs; (ix)use good-faith efforts to resolve other issues presented to it by either Party pertaining to the administration of each of the Research Programs or other matters covered by this Agreement; and(x)facilitate communication between the Parties and provide a forum to review any technology transfer matters.(c)Reporting. Each Party shall keep the JSC informed on the progress of the activities under each of the Research Programs then currently ongoing under the Research Plans, including delivering quarterly written updates of its progress under each of the Research Plans to the JSC at least one (1) week in advance of each JSC meeting.(d)Meetings. During the performance of any of the Research Plans by Gemma, the JSC will meet at least quarterly. Following the completion of Gemmaâ€™s performance of all of the Research Plans, the Parties may agree to meet to discuss items previously addressed by the JSC. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least two (2) meetings per Calendar Year will be in person unless the Parties mutually agree in writing to waive such requirement. In-person JSC meetings will be held at locations alternately selected by Gemma and by Passage; provided, however, 21â€Œâ€‹â€‹that Passage shall reimburse Gemma for its JSC representativesâ€™ costs in connection with attending such in-person JSC meeting at a Passage-selected location other than Gemma. Meetings of the JSC will be effective only if at all representatives of each Party are present or participating in such meeting. The JSC shall keep accurate minutes of its deliberations which shall record all proposed decisions and all actions recommended or taken. The secretary of the JSC (as appointed by the members of the JSC) shall be responsible for the preparation of draft minutes. Draft minutes shall be sent to all members of the JSC within [*] after each meeting and shall be approved, if appropriate, at the next meeting. All records of the JSC shall at all times be available to both Gemma and Passage.(e)Decision-Making. The representatives from each Party on the JSC will have, collectively, one (1) vote on behalf of that Party, and all decision making will be by [*]. If the JSC is unable to reach agreement on any issue or matter for which it is responsible, such disputed matter will be escalated to Passageâ€™s Chief Executive Officer and Gemmaâ€™s Chief Executive Officer, for discussion in good faith. In the event that after escalation the Parties are unable to reach agreement with respect to the disputed matter, then (1) for disputed matters relating to submissions to [*], and (2) for all other disputed matters: (i) [*] or (ii) [*].2.11.2Alliance Managers. Each Party will appoint a representative to act as its alliance manager under this Agreement (each, an â€œAlliance Managerâ€). Alliance Managers will attend JSC meetings as non-member participants. Each Alliance Manager will be responsible for:(a)promoting effective communication between the Parties;(b)developing a mutually agreed alliance plan covering any activities and systems that the Parties need to implement within the first [*] after the Effective Date to support each of the Research Programs;(c)supporting the members (including secretary) of the JSC with organization of meetings, information exchange, meeting minutes, and facilitating dispute resolution as necessary;(d)preparing status and progress reports on the above as determined necessary by the JSC; and(e)ensuring proper approval of publications prior to submission as required in SectionÂ 7.4.Article 3â€‹LICENSES AND OTHER RIGHTS3.1Grant of License.3.1.1Subject to the terms and conditions of this Agreement, Gemma hereby grants to Passage the following rights and licenses (collectively, the â€œLicenseâ€):(a)an exclusive, worldwide, Royalty-bearing right and license (with the right to sublicense through multiple tiers, subject to the provisions of Section 3.4), under (i) Licensed Patent Rights A, to make, have made, use, sell, offer for sale and 22â€Œâ€‹â€‹import Licensed Products for the Indications ([*]), in the Field of Use during the Term, and (ii) Licensed Patent Rights B to make, have made, use, sell, offer for sale and import Designated Products for the Indications ([*]) in the Field of Use during the Term; provided, for clarity, [*];(b)a non-exclusive, world-wide Royalty-bearing right and license [*], under Licensed Know-How and Licensed Materials (and Gemmaâ€™s intellectual property rights therein) to use and practice the same in order to make, have made, use, sell, offer for sale and import Licensed Products for the Indications ([*]) in the Field of Use during the Term; and(c)a non-exclusive, worldwide, Royalty-bearing right and license under Licensed Patent Rights B, without the right to sublicense ([*]), to make, have made, use, sell, offer for sale and import Licensed Products for the Indications ([*]) in the Field of Use during the Term.(d)The licenses set forth in subsections (a) through (c) above, for a Specified Licensed Product, are hereby automatically expanded to all indications within the CNS Field to the extent that such licensing would not violate a Specified Obligation. Furthermore, to the extent that Passage desires to have the License cover one or more additional indications for the Specified Licensed Product (other than the named Indication for such Specified Licensed Product) outside the CNS Field for the Field of Use during the Term for an existing Specified Licensed Product that has been licensed for a named Indication, then Passage shall provide written notice to Gemma [*]. Such additional indication will thereupon automatically be covered by the License (for such existing Specified Licensed Product) to the extent: (A) [*], and (B) [*]. If the condition in the preceding clause (A) is not satisfied, Gemma will inform Passage [*] and if so, the Parties shall, if requested by Passage, discuss and negotiate in good faith for the inclusion of such additional indication in the License for such Specified Licensed Product [*].(e)Without limiting the foregoing, Gemma will not license or grant any other rights in or to, any Licensed Patent Rights, Licensed Know-How, DRG Patent Rights or DRG Know-How to any Third Party for any Specified Licensed Product under this Agreement for any indication in the Field of Use.(f)If, during the [*], additional Patent Rights Controlled by Gemma arising from research solely conducted by Gemma are identified by either Party as necessary for the development and commercialization of Licensed Products for the Indications for the Field of Use, [*].3.1.2Subject to the terms and conditions of this Agreement, Gemma hereby grants to Passage the following license to the DRG Technology (collectively, the â€œDRG Licenseâ€):(a)a non-exclusive, worldwide, Royalty-bearing right and license ([*]), under Gemma DRG Patent Rights to make, have made, use, sell, offer for sale and import [*] for the Indications in the Field of Use during the Term; and(b)a non-exclusive, worldwide, Royalty-bearing right and license ([*]), under Gemma DRG Know-How to make, have made, use, sell, offer for sale and import [*] for the Indications in the Field of Use during the Term. 23â€Œâ€‹â€‹3.1.3Notwithstanding anything to the contrary, to the extent the License with respect to a Licensed Product is expanded to additional indications as set forth in Section 3.1.1(d), the DRG License will automatically be expanded to the same indications other than the DRG Excluded Indications for so long as such DRG Excluded Indications are exclusively licensed from Gemma to a Third Party, it being understood that such expansion shall be on a non-exclusive basis. 3.2Retained Rights.3.2.1Notwithstanding the License, Gemma retains the right under Licensed Patent Rights, Discovery Patent Rights and DRG Patent Rights to: (a) conduct research, clinical, Â and patient care activities itself, including, but not limited to sponsored research, and (b) authorize non-commercial Third Parties to conduct educational, research, clinical and patient care activities; [*].3.3U.S. Government Rights.The License is expressly subject to all applicable provisions of any license to the United States Government executed by Gemma and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. Â§Â§200-212, applicable governmental implementing regulations, and the U.S. Government sponsored research agreement or other guidelines, including that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States.3.4Grant of Sublicense by Passage.3.4.1Gemma grants to Passage the right to grant sublicenses, in whole or in part, under the License (each, a â€œSublicenseâ€) subject to the terms and conditions of this Agreement and specifically this Section 3.4. The term â€œSublicenseâ€ shall include any grant of rights under the License by a Sublicensee to any downstream Third Party, and such downstream Third Party shall also be considered a Sublicensee for purposes of this Agreement.3.4.2All Sublicenses will (a) be issued in writing, (b) to the extent applicable, include all of the rights of Gemma and require the performance of obligations due to Gemma (and, if applicable, the U.S. Government under 35 U.S.C. Â§Â§200-212) contained in this Agreement, and (c) include no less than the following terms and conditions:(a)Reasonable record keeping, audit and reporting obligations sufficient to enable Passage and Gemma to reasonably verify the payments due to Passage and Gemma under such Sublicense and to reasonably monitor such Sublicenseeâ€™s progress in developing and/or commercializing Licensed Product, provided that such obligations shall be no less stringent that those provided in this Agreement for Passage.(b)Infringement and enforcement provisions that do not conflict with the restrictions and procedural requirements imposed on Passage and do not provide greater rights to Sublicensee than as provided in Section 6.3.(c)Confidentiality provisions with respect to Confidential Information of Gemma consistent with the restrictions on Passage in Article 7 of this Agreement. 24â€Œâ€‹â€‹(d)Covenants by Sublicensee that are equivalent to those made by Passage in SectionÂ 8.5.(e)A requirement of indemnification of Gemma by Sublicensee that is equivalent to the indemnification of Gemma by Passage under Section 9.1 of this Agreement.(f)A requirement of obtaining and maintaining insurance by Sublicensee that is equivalent to the insurance requirements of Passage under Section 9.4 of this Agreement, including coverage under such insurance of Gemma as provided in Section 9.4.(g)Restriction on use of Gemmaâ€™s names, etc. consistent with Section 11.4 of this Agreement.(h)A requirement of antidiscrimination by Sublicensee no less stringent than that provided in Section 11.5 of this Agreement.(i)A requirement that Gemma is a third party beneficiary of such Sublicense.Any Sublicense that does not include all of the terms and conditions set forth in this SectionÂ 3.4.2 or which is not issued in accordance with the terms and conditions set forth in this Section 3.4, shall be considered null and void with no further notice from Gemma unless separately approved by Gemma in writing.3.4.3Within [*] after of the execution of a Sublicense Document, Passage shall provide a complete and accurate copy of such Sublicense Document to Gemma, in the English Language. Gemmaâ€™s receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Gemma or obligation of Passage under this Agreement.3.4.4Passage shall provide an annual Sublicense Development Report on or before December 1 of each year during the Term (â€œSDR Reportâ€), a form of which is attached hereto as Exhibit F.3.5Delivery of Know-How.Upon completion of a Research Program on a Licensed Product-by Licensed Product basis, [*], Gemma shall, upon Passageâ€™s reasonable written request and at Passageâ€™s cost and expense, disclose and deliver Licensed Know-How and/or Licensed Materials to Passage applicable to the Licensed Product, and [*] such Licensed Know-How and/or Licensed Materials for the exploitation of the License.3.6No Implied License.Each Party acknowledges that the rights and licenses granted in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to any Know-How, patent or other intellectual property right that are not specifically granted herein are reserved to the owner thereof. 25â€Œâ€‹â€‹Article 4â€‹FINANCIAL PROVISIONS4.1Payments.4.1.1New Indication Option Payment. Within [*] after Passageâ€™s exercise of each of up to four (4) New Indication Options, Passage will pay to Gemma a non-refundable, non-creditable payment in the aggregate amount of One Million US Dollars ($1,000,000) by wire transfer of immediately available funds (â€œNew Indication Option Feeâ€); provided that if a New Indication is added as an Indication prior to the generation of pre-clinical pharmacology data, then the payment will be made as follows: Five Hundred Thousand US Dollars ($500,000) at exercise and Five Hundred Thousand US Dollars ($500,000) at the generation of pre-clinical pharmacology data.4.1.2New Indication Multiplier. Â Notwithstanding anything herein, for any New Indication that is added to the License upon exercise by Passage of a New Indication Option prior to completion of the IND-enabling studies, the milestone, sublicensing fee percentages and Royalties outlined below shall apply as set forth in this Agreement; provided, that for any New Indication that is added to the License [*], a multiplier of [*] shall be applied to each of [*]. 4.2Milestone Payments. 4.2.1Development Milestones. (a)As partial consideration for the License, Passage will pay Gemma the following milestone payments (each, a â€œDevelopment Milestone Paymentâ€) upon the achievement of the corresponding milestone for each Licensed Product for the first Indication (each, a â€œDevelopment Milestoneâ€), whether achieved by Passage or an Affiliate or Sublicensee. Passage shall promptly notify Gemma in writing of the achievement of any such Development Milestone and Passage shall pay Gemma in full the corresponding Development Milestone Payment within [*] after such achievement. For clarity, each Development Milestone Payment is non- refundable, and is not an advance against Royalties due to Gemma or any other amounts due to Gemma.Development MilestoneMilestone Payment(in U.S. dollars) for each Licensed Product for the first Indication (except as noted in the column to the right)Milestone Payment (in U.S. dollars) for Licensed Product arising from the TLE Research Programâ€‹[*][*][*][*][*][*][*][*][*][*][*][*]â€‹â€‹(b)Notwithstanding anything to the contrary, to the extent a product is a Licensed Product solely by virtue of incorporating DRG Technology, and no other Licensed Patent Right or Licensed Know-How, the milestone amounts set forth in the table 26â€Œâ€‹â€‹above in Section 4.2.1(a) solely for such Licensed Product shall be replaced with the amounts set forth in the table below:Development MilestoneMilestone Payment(in U.S. dollars)â€‹[*][*][*][*][*][*]â€‹â€‹(c)Each time a Development Milestone is achieved for a Licensed Product for an Indication, then any other Development Milestone Payments with respect to earlier Development Milestones that have not yet been paid will be due and payable together with the Development Milestone Payment for the Development Milestone that is actually achieved.(d)Notwithstanding the foregoing, in the event that the Licensed Product is applicable to any indication(s) outside of the named Indication in the applicable Research Program (and Gemma has the right to grant a License to such additional indication in accordance with Section 3.1), the foregoing milestones shall be due and payable by Passage to Gemma on such additional indication(s) as follows: (i) for a second indication of a Licensed Product, Passage shall pay Gemma [*] of the foregoing Development Milestones for the Licensed Product for the second indication, and (ii) for a third indication of the Licensed Product, Passage shall pay Gemma [*] of the foregoing Development Milestones for the Licensed Product for such third indication. No Development Milestones will apply to the fourth (or any later) indication of a given Licensed Product.(e)For clarity, Development Milestone Payments are due and payable on Licensed Product and on products that, upon Regulatory Approval, would become Licensed Product.4.2.2Commercial Milestone Payments.(a)As additional consideration for the License, Passage will pay Gemma the following commercial milestone payments (each, a â€œCommercial Milestone Paymentâ€) upon the achievement by Passage or an Affiliate or Sublicensee of the corresponding milestone (each, a â€œCommercial Milestoneâ€), that is, when Â worldwide Net Sales of a Licensed Product in a Calendar Year first reach the respective thresholds indicated below. Passage shall promptly notify Gemma in writing of the achievement of any such Commercial Milestone and Passage shall pay Gemma in full the corresponding Commercial Milestone Payment within [*] after such achievement. For clarity, [*].Commercial Milestone Event (payable once per Licensed Product)One-Time Milestone Payment(U.S. dollars)[*][*][*][*][*] 27â€Œâ€‹â€‹[*][*]â€‹â€‹(b)For clarity, the foregoing Commercial Milestone Payments shall be due once per Licensed Product.4.3Royalties.4.3.1Royalty. (a)As further consideration for the License, on a Licensed Product-by-Licensed Product and country-by-country basis during the Royalty Period, Passage shall pay to Gemma a non-refundable, non-creditable royalty on Net Sales of each Licensed Product (â€œRoyaltyâ€) as set forth below:Annual Worldwide Net Sales(of the applicable Licensed Product)Royalty RateLess than [*][*]Greater than or equal to [*] and less than or equal to [*][*]Greater than [*][*]â€‹â€‹For clarity, the foregoing Royalty rates are tiered such that each rate applies only to the portion of annual Net Sales that is within the corresponding tier. That is, within any given Calendar Year, the first [*] of Net Sales of a given Licensed Product will accrue Royalties at [*] the next [*] of Net Sales of such Licensed Product will accrue Royalties at [*], and any Net Sales of such Licensed Product in excess of [*] will

accrue Royalties at [*].(b)Notwithstanding anything to the contrary, to the extent a product is a Licensed Product solely by virtue of incorporating DRG Technology, and no other Licensed Patent Right or Licensed Know-How, then the royalty rates set forth in the table above in Section 4.3.1(a) solely for such Licensed Product shall be replaced by a single royalty rate equal to [*] of Net Sales for such Licensed Product.4.3.2Royalty Term. Passageâ€™s obligation to pay Gemma the Royalty will continue on a country- by-country and Licensed Product-by-Licensed Product basis from the date of First Commercial Sale of such Licensed Product in such country until the latest of (a) the expiration of the last Valid Claim within the Licensed Patent Rights covering such Licensed Product in such country, (b) the expiration of the data exclusivity term conferred by the applicable Regulatory Authority in such country with respect to such Licensed Product (e.g., such as in the case of an orphan drug), and (c) the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product in such country, subject to the terms of Section 6.5 (such royalty period, the â€œRoyalty Periodâ€).4.3.3Step-Down. On a country-by-country and Licensed Product-by-Licensed Product basis, during any portion of the Royalty Period in which the applicable Licensed Product is not covered by at least one Valid Claim in the applicable country and is not subject to data exclusivity conferred by the applicable Regulatory Authority: (a) the Royalty rate under Section 4.3.1 shall be reduced to [*] of the Royalty rate otherwise payable pursuant to Section 4.3.1; and (b) no Royalty at all will apply to such Licensed Product [*].4.3.4Royalty Reductions. 28â€Œâ€‹â€‹(a)Notwithstanding anything in this Section 4.3, in the event that Gemma or Passage receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. If any Third Party obtains a Compulsory License in any country, then: (i) Gemma or Passage (whoever has first notice) shall promptly notify the other Party; and (ii) beginning as of the date the Third Party obtained such Compulsory License in such country, the Royalty rate payable under this Section 4.3 to Gemma for Net Sales in such country will be adjusted to [*].(b)Third Party Licenses.(i)If after the Effective Date, Passage determines upon the advice of outside intellectual property counsel that a license to Patent Rights from a Third Party is reasonably necessary to develop, commercialize, or manufacture a Licensed Product, Passage may obtain such a Third Party license to such Patent Rights.(ii)Passage may deduct from any Royalty payments due to Gemma under Section 4.3.1 of this Agreement an amount equal to (A) [*], and (B) [*].(iii)In the event that one or more Generic Product(s) with respect to a particular Licensed Product enter(s) the market in a particular country, and such Generic Product(s) in the aggregate have a market share of [*] or more in that country, Passage may reduce the Royalty payments for Sales of such Licensed Product in such country by [*]; provided that if Passage reduced the Royalty payments under this Section 4.3.4(b)(iii), Passage shall resume making Royalty payments without reduction under this Section 4.3.4(b)(iii) as of the earlier of (A) no Generic Product being sold for at least [*] in such country and (B) a court of competent jurisdiction determining that a Valid Claim of a Licensed Patent Right is valid and infringed by such Generic Product in such country.(iv)Notwithstanding the foregoing, in no event will the deductions under this Section 4.3.4(b) reduce the Royalty payable in respect of Net Sales of such Licensed Product in such country by more than [*] (the â€œMaximum Anti-Stacking Reductionâ€) of the Royalty as set forth in SectionÂ 4.3.1 above, except for any deductions under Section 4.3.4(b)(ii)(A).4.3.5Calculations. Passage must pay Royalties owed to Gemma on a Calendar Quarter basis on or before the following dates:(a)[*] for any Sales that took place in the Calendar Quarter ending December 31, of the prior year;(b)[*] for any Sales that took place in the Calendar Quarter ending March 31 of such Calendar Year;(c)[*] for any Sales that took place in the Calendar Quarter ending June 30 of such Calendar Year; and(d)[*] for any Sales that took place in the Calendar Quarter ending September 30 of such Calendar Year. 29â€Œâ€‹â€‹4.4Gemma Sublicense Income. 4.4.1For any given Licensed Product, Passage will pay to Gemma the following percentage of Sublicense Income (â€œGemma Sublicense Incomeâ€) received by Passage from a Sublicensee (with no rights of apportionment):Stage in Licensed Product development at which sublicense is granted by Passage% of Sublicense IncomePayable to Gemma[*][*][*][*][*]â€‹4.4.2Passage will make such payment to Gemma on or before the following dates:(a)[*] for any Sublicense Income received by Passage in the Calendar Quarter ending December 31, of the prior year;(b)[*] for any Sublicense Income received by Passage in the Calendar Quarter ending March 31 of such Calendar Year;(c)[*] for any Sublicense Income received by Passage in the Calendar Quarter ending June 30 of such Calendar Year; and(d)[*] for any Sublicense Income received by Passage in the Calendar Quarter ending September 30 of such Calendar Year.4.5Payment and Currency.Payments under this Agreement shall be made in USD. Payments to a Party shall be made by electronic wire transfer of immediately available funds to the account of the other Party, as designated in writing to the paying Party. Â All Royalties payable under this Agreement shall be calculated first in the currency of the jurisdiction in which the payment was made, and if not in the United States, then converted into USD. The exchange rate for such conversion shall be the average of the rates quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter in respect of which such Royalty payment made.4.6Royalty and Gemma Sublicense Income Reports.Within [*] after the end of each Calendar Quarter, Passage shall deliver to Gemma a report (â€œFinancial Reportâ€) setting out all details necessary to calculate the Royalty and Gemma Sublicense Income due under this Article 4 for such Calendar Quarter, including:(a)[*];(b)Gross sales and Net Sales of each Licensed Product made by Passage, its Affiliates and Sublicensees;(c)Royalties;(d)Sublicense Income and the calculation of Gemma Sublicense Income; 30â€Œâ€‹â€‹(e)The method and currency exchange rates (if any) used to calculate the Royalties and Gemma Sublicense Income;(f)A specification of all deductions and their dollar value that were taken to calculate Net Sales; (g)A list of all countries in which Licensed Product is being manufactured (on a Licensed Product-by-Licensed Product basis); and(h)Date of First Commercial Sale in the United States (this need only be reported in the first Financial Report following such First Commercial Sale in the United States).Each Financial Report shall be in the form of the sample report attached hereto as Exhibit G.4.7Late Payments.In addition to any other remedies available to Gemma, including the right to terminate this Agreement as provided in Section 10.3, any failure by Passage to make a payment within [*] after the date when due shall obligate Passage to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Gemma at a rate per annum equal to [*], or the highest rate allowed by Law, whichever is lower.4.8Default Payment.In the event of default in payment of any payment owing to Gemma under the terms of this Agreement, and if it becomes necessary for Gemma to undertake legal action to collect said payment, Passage shall pay reasonable, documented legal fees and costs incurred in connection therewith.4.9Accounting.Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.4.10Books and Records.Passage will keep accurate books and records of all Licensed Products developed, manufactured, used or sold and all Sublicenses, collaboration agreements and joint venture agreements entered into by Passage that involve Licensed Patent Rights. Passage will preserve these books and records for at least [*] from the date of the Financial Report to which they pertain. Upon reasonable notice, key personnel, books and records will be made reasonably available and will be open to examination by representatives or agents of Gemma during regular office hours to determine their accuracy and assess Passageâ€™s compliance with the terms of this Agreement, provided that Passage shall not have an obligation to provide access more than once in any given [*] period.4.11Audits.In addition to the right of Gemma to examine the books and records and interview key personnel as provided in Section 4.10 above, Gemma, at its own cost, through an independent auditor reasonably acceptable to Passage (and who has executed an appropriate confidentiality agreement 31â€Œâ€‹â€‹reasonably acceptable to Passage that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Gemma), may inspect and audit the relevant records of Passage pertaining to the calculation of any Development Milestone Payments, Commercial Milestone Payments, Royalties and Gemma Sublicense Income due to Gemma under this Agreement. Passage shall provide such auditors with access to the relevant records during reasonable business hours. Such access need not be given to any such set of records more often than once each year or more than [*] after the date of any report to be audited. Gemma shall provide Passage with written notice of its election to inspect and audit the records related to the Development Milestone Payments, Commercial Milestone Payments and Royalties due hereunder not less than [*] prior to the proposed date of review of Passageâ€™s records by Gemmaâ€™s auditors. Should the auditor find any underpayment of Development Milestone Payments, Commercial Milestone Payments, Royalties or Gemma Sublicense Income by Passage, Passage shall (a) promptly pay Gemma the amount of such underpayment; (b) reimburse Gemma for the cost of the audit, if such underpayment equals or exceeds the higher of (i) [*] or (ii) [*] of combined Development Milestone Payments, Commercial Milestone Payments, Royalties and Gemma Sublicense Income paid during the time period audited; and (c) provide such auditors with an audit right exercisable within [*] after Gemma receives the audit report. If the auditor finds overpayment by Passage, then Passage shall have the right to deduct the overpayment from any future Development Milestone Payments, Commercial Milestone Payments, Royalties or Sublicense Income due to Gemma by Passage or, if no such future Development Milestone Payments, Commercial Milestone Payments, Royalties or Sublicense Income are payable, then Gemma shall refund the overpayment to Passage within [*] after Gemma receives the audit report. [*].4.12Taxes.All payments made by Passage to Gemma under this Agreement shall be made free and clear of and without any deduction for or on account of any Taxes on or with respect to such payments.Article 5â€‹CLINICAL DEVELOPMENT, REGULATORY AFFAIRS; COMMERCIALIZATION5.1Development Plan.Passage shall provide Gemma with a development plan no later than [*] during the Term. The development plan shall include a timeline for detailed activities to be conducted by Passage, its Affiliates and Sublicensees, and Passage shall provide Gemma with [*] progress reports regarding achievements and activities under such development plan. For clarity, [*].5.2Clinical.Passage shall have the first right to sponsor all clinical activities and lead regulatory interactions for the Licensed Products for each Indication under this Agreement. Without limiting the foregoing, Passage will have the first option, but not an obligation, to conduct a FIH Clinical Study for each Licensed Product developed under the Research Programs. Passage will consider in good faith using Gemma as a study site for one or more studies where Gemma can reasonably demonstrate that Gemmaâ€™s capabilities and costs are reasonably comparable to other potential study sites. If Gemma (in its sole discretion) is willing and able to conduct a Clinical Study for a Licensed Product developed under the Research Programs, the Parties will negotiate a separate clinical trial agreement and a separate clinical trial budget prior to initiation of such Clinical Study. For clarity, any Clinical Study funding by Passage shall be separate and in addition to the Research Support Amount. 32â€Œâ€‹â€‹5.3Commercialization.Passage will have sole responsibility for and sole decision-making over all commercialization activities for the Licensed Products for the Indications in the Field of Use, and will be solely responsible for the associated costs of such commercialization activities.5.4Manufacturing.Except as otherwise provided in this Agreement or in the Research Plans, Passage will have responsibility for and decision-making authority over all manufacturing activities and associated costs for the clinical development (including GMP manufacturing for clinical trials) and commercialization of the Licensed Products in the Field of Use for the Indications post-DTP for such Licensed Product. Passage and Gemma will have joint responsibility for and shall mutually agree upon any manufacturing activities for pre-clinical manufacturing, [*] and at Passageâ€™s cost.5.5Regulatory.5.5.1Subject to Section 2.11.1(b), Passage will have responsibility for and decision-making over regulatory activities for the Licensed Products for the Indications in the Field of Use. Passage will have the right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings), with regard to Licensed Products for the Indications in the Field of Use; [*]. Passage will lead and have control over preparing and submitting all regulatory filings related to the Licensed Products for the Indications in the Field of Use, including all applications for Regulatory Approval, provided, however, that Passage shall provide Gemma with copies of all such applications prior to submission to the extent such submission includes any Research Results or Confidential Information of Gemma. Passage will own any and all applications for Regulatory Approvals (including INDs), Regulatory Approvals, and other regulatory filings related to the Licensed Products for the Indications in the Field of Use, which will be held in the name of Passage or its designees.5.5.2Gemma will cooperate with any reasonable request from Passage with respect to obtaining any Regulatory Approval for a Licensed Product for an Indication in the Field of Use including, at Passageâ€™s cost: (a) [*], (b) [*], and (c) [*].5.6General Diligence.Passage will use Commercially Reasonable Efforts to actively develop, obtain Regulatory Approval and commercialize at least one Licensed Product in each Indication within the Field of Use.5.7Diligence Events.5.7.1Passage, itself or through any of its Affiliates or Sublicensees, shall achieve each of the following Diligence Events by the corresponding Achievement Date for each Licensed Product:Diligence EventAchievement Date [*][*][*][*][*][*] 33â€Œâ€‹â€‹â€‹Gemma acknowledges that the timeline for each Achievement Date is based on the assumption that development and commercialization of a Licensed Product does not encounter material regulatory or other delays for reasons outside of Passageâ€™s reasonable control. Where such circumstances exist, Gemma agrees to negotiate in good faith with Passage, upon Passageâ€™s written request and provided such request is made at least [*] prior to the Achievement Date for a Diligence Event, an extension of the Achievement Date for a Diligence Event for such Licensed Product as reasonably requested by Passage. If the Parties have not agreed on a requested extension within [*] after such request, [*].To the extent Passage has achieved any Diligence Event by the corresponding Achievement Date in relation to a given Licensed Product for an Indication, Passage will be deemed to have also met its diligence obligations under Section 5.6 with respect to such Licensed Product for such associated Indication through the corresponding Achievement Date.5.8Progress Reports.5.8.1After performance of the applicable Research Plan by Gemma but prior to the First Commercial Sale of a Licensed Product in the respective Indication, Passage on [*], but in no event later than [*], shall submit to Gemma a progress report (each, a â€œProgress Reportâ€) covering Passageâ€™s (and any Affiliatesâ€™ and Sublicenseesâ€™) activities related to the development of all Licensed Products in each Indication and the obtaining of Regulatory Approvals necessary for commercialization of Licensed Products.5.8.2Each Progress Report must include all of the following for each annual period:(a)Summary of material development activities;(b)Summary of material commercialization activities;(c)Identification of filings for Regulatory Approval and other material correspondence with Regulatory Authorities;(d)An updated SDR Report listing of any and all Sublicenses granted by Passage; and(e)The names and addresses of all Sublicensees, and a current and valid phone number and e-mail address for a principal point of contact at each such Sublicensee who is responsible for administering the Sublicensee.Article 6â€‹INTELLECTUAL PROPERTY6.1Patent Filing Prosecution and Maintenance. 6.1.1Licensed Patent Rights, Discovery Patent Rights, and DRG Patent Rights will be held in the name of Gemma (or Penn, with respect to the Patent Rights licensed to Gemma pursuant to the Upstream License Agreement) and obtained with counsel selected by Gemma (or Penn, as applicable) and reasonably acceptable to Passage (â€œPatent Counselâ€). Gemma or Penn (as applicable) shall control all actions and decisions with respect to the filing, prosecution and maintenance of Licensed Patent Rights, Discovery Patent Rights, and DRG Patent Rights. Gemma will provide Passage with advance copies of filings of the 34â€Œâ€‹â€‹Licensed Patent Rights and Gemma will consider (and require Penn to consider, as applicable) in good faith reasonable comments and suggestions made by Passage to such filings, and [*] (collectively, the â€œProduct Specific Patent Rightsâ€), Gemma will incorporate (or request that Penn incorporate) any reasonable comments or suggestions by Passage with respect to same. Gemma will instruct (or request Penn to instruct) Patent Counsel to copy Passage on all correspondence related to Licensed Patent Rights A and Licensed Patent Rights B (including copies of each patent application, office action, response to office action, request for terminal disclaimer, and request for reissue or reexamination of any patent or patent application) and to interact with Passage with respect to the preparation, filing, prosecution and maintenance of such Licensed Patent Rights A and Licensed Patent Rights B. Gemma has the right to take action to preserve rights and minimize cost [*], and will use commercially reasonable efforts to not allow any Licensed Patent Rights and DRG Patent Rights it (or Penn, as applicable) prosecutes and maintains and for which Passage is licensed and is underwriting the costs to lapse or become abandoned without Passageâ€™s written authorization under this Agreement, [*], provided that, Gemma shall have no requirement to file, prosecute, or maintain Licensed Patent Rights, Discovery Patent Rights or DRG Patent Rights if Passage is not current with the Patent Cost obligations as set forth in this Agreement. For the purposes of this Agreement, â€œmaintenanceâ€ of the Licensed Patent Rights, Discovery Patent Rights, and DRG Patent Rights includes [*], provided Gemmaâ€™s participation in such proceedings is undertaken in good-faith consultation with Passage. For further clarity, [*] will be handled pursuant to the provisions of Section 6.3.6.1.2Passage has the right to request a country filing via a written request to Gemma [*] prior to the deadline set by the patent office in the country or regulatory jurisdiction in which the filing is to take place (â€œProsecution Requestâ€), and Gemma shall in connection with Section 6.1.1 provide written notice to Passage of filing, prosecution and maintenance with respect to the applicable Licensed Patent Rights. If Gemma or Penn files a patent application, or prosecutes or maintains any Licensed Patent Rights in such country or regulatory jurisdiction, Passage shall, in connection with Section 6.2, be responsible for the pro rata costs of such filing, prosecution or maintenance of such Licensed Patent Rights. The failure to make a given Prosecution Request by such deadline will be considered an election not to secure the Patent Right associated with the specific phase of patent prosecution in such country or regulatory jurisdiction, and such patent application(s) and/or patent(s) will, upon the expiration of such [*] period, not be part of Licensed Patent Rights and therefore not subject to the terms of this Agreement, including the License, and Passage will have no further rights or licenses to such patent application(s) and/or patent(s) in such country or regulatory jurisdiction.6.2Patent Costs.6.2.1Passage will bear all out-of-pocket costs for the filing, prosecution and maintenance of Licensed Patent Rights, Discovery Patent Rights and DRG Patent Rights incurred by Gemma or owed to Penn by Gemma, including all accrued attorney fees, expenses, official and filing fees incurred by Gemma or owed to Penn by Gemma during the Term (â€œPatent Costsâ€), on a pro rata basis (as described below) where applicable. For Licensed Patent Rights, Discovery Patent Rights and DRG Patent Rights licensed or optioned to more than one licensee and prosecuted and maintained by Gemma or Penn, Passage shall be responsible for payment to Gemma of Passageâ€™s pro rata share of such Patent Costs based on the total number of licensees (which shall include Gemma) for such Licensed Patent Rights, Discovery Patent

Rights and DRG Patent Rights (which Gemma will disclose to 35â€Œâ€‹â€‹Passage upon Passageâ€™s exercise of an applicable option, and whenever such number changes, and at any other time upon Passageâ€™s reasonable written request). 6.2.2At any time, at Gemmaâ€™s request, Passage shall pay its relevant share in advance of the Patent Counselâ€™s estimated costs for undertaking material patent actions before Gemma or Penn, as applicable, authorizes the Patent Counsel to proceed (â€œAdvance Paymentâ€). Notwithstanding whether Passage makes an Advance Payment for any patent action, Passage shall bear all Patent Costs incurred by Gemma or owed to Penn by Gemma during the Term (on a pro rata basis as applicable) and shall pay such amounts within [*] after Passageâ€™s receipt of any invoice for such patent actions. For clarity, [*].6.2.3In the event that Passage provides Gemma at least [*] advance written notice to elect not to pay Patent Costs for any Licensed Patent Right, Discovery Patent Right, or DRG Patent Right in any country or regulatory jurisdiction, upon the effective date of such notice, such patent or patent application shall no longer be part of the License granted to Passage in Section 3.1 or part of the Licensed Patent Rights for purposes of this Agreement (including the provisions of this Section 6.2) and Passage shall not be entitled to receive a license to such Licensed Patent Right, Discovery Patent Right, or DRG Patent Right in such country or regulatory jurisdiction in the future. In addition, for such rejected Licensed Patent Right or Discovery Patent Right, the Licensing Exclusivity Period or ability to add such rejected Licensed Patent Right or Discovery Patent Right to the license grant as set forth in Section 2.6.3 shall terminate immediately.6.2.4Passage shall also have the right, on a DRG Patent Right-by-DRG Patent Right and country-by-country basis, to (a) elect not to fund at the time of disclosure, or (b) elect not to continue to fund, in each case (a) and (b), its pro rata share (as determined pursuant to Section 6.2.1 above) of the Patent Costs with respect to any DRG Patent Right(s) prosecuted and maintained by Gemma or Penn in a particular country or regulatory jurisdiction, which election may be made by Passage upon [*] prior written notice to Gemma (â€œDRG Election Noticeâ€). If Passage delivers a DRG Election Notice to Gemma, following the expiration of such [*] period, Passage shall have no further obligation to pay Patent Costs with respect to any DRG Patent Right identified in such DRG Election Notice in any country or regulatory jurisdiction identified in such DRG Election Notice and any such Patent Right in such country or regulatory jurisdiction shall thereafter be excluded from the DRG Patent Rights.6.3Infringement. 6.3.1If either Party believes that an infringement by a Third Party with respect to any Licensed Patent Right or DRG Patent Right is occurring or may potentially occur, the knowledgeable Party will provide the other Party with (a) written notice of such infringement or potential infringement and (b) evidence of such infringement or potential infringement (the â€œInfringement Noticeâ€). Passage shall [*] without first obtaining the written consent of Gemma, which consent will not be unreasonably withheld. If Passage [*], then Passageâ€™s right to initiate a suit under Section 6.3.2 below will terminate immediately without the obligation of Gemma to provide notice to Passage. Both Gemma and Passage will use diligent efforts to cooperate with each other to terminate such infringement without litigation.6.3.2If infringing activity [*] has not been abated within [*] following the date the Infringement Notice for such activity was provided, then (except as otherwise provided in Section 6.3.4) 36â€Œâ€‹â€‹during [*], the â€œExclusive Licensed Patent Rightsâ€), and the infringing product is [*], Passage may institute suit for patent infringement of such [*] against the infringer after providing Gemma (a) [*] and (b) [*]. For clarity, [*]. Gemma may voluntarily join such suit at Passageâ€™s reasonable expense, [*]. If in a claim initiated by Passage, Gemma is involuntarily joined other than by Passage, then Passage [*]. Passage shall be free to enter into a settlement, consent judgment or other voluntary disposition, provided that any settlement, consent judgment or other voluntary disposition that (i) [*] or (ii) [*]. Passageâ€™s request for such approval shall include complete copies of final settlement documents, a detailed summary of such settlement, and any other information material to such settlement. Gemma shall provide Passage notice of its approval or denial within [*] after receipt of any request for such approval from Passage, provided that (A) [*] and (B) [*].6.3.3If, within [*] following the date the Infringement Notice was provided, infringing activity of [*] has not been abated and if Passage has not brought suit against the infringer, then Gemma may [*]. If Gemma institutes such suit, then Passage [*].6.3.4Notwithstanding Sections 6.3.2 and 6.3.3, (a) in the event that any Licensed Patent Rights are infringed by a Third Party [*] or (b) if any of the infringed Licensed Patent Rights are [*], the Parties shall discuss, and will mutually agree, in writing, as to how to handle such infringement by such Third Party. Furthermore, with respect to any Licensed Patent Rights A that are not Product Specific Patent Rights, and/or any Licensed Patent Rights B, Passage [*]. For clarity, [*]. Gemma or Penn shall [*] right to enforce Licensed Patent Rights B, unless otherwise agreed in writing by the Parties ([*]).6.3.5Any recovery or settlement received in connection with any suit will first be [*] and next [*]. Any remaining recoveries shall be allocated as follows:For any portion of the recovery or settlement, other than for amounts attributable and paid as enhanced damages for [*]:(a)for any suit that is initiated by Passage and in which Gemma was not a party in the litigation, Gemma shall receive [*] of the recovery and Passage shall receive the remainder; and(b)for any suit that is initiated by Passage or Gemma and that the other Party joins voluntarily ([*]) or involuntarily, the non-initiating Party shall receive [*] of such recovery, while the initiating Party shall receive the remainder.For any portion of the recovery or settlement paid as enhanced damages for [*]:(c)for any suit that is initiated by Passage or Gemma and the other Party joins voluntarily ([*]) or involuntarily, Gemma shall receive [*] and Passage shall receive the remainder; and(d)for any suit that is initiated by Passage and in which Gemma was not a party in the litigation, Gemma shall receive [*] and Passage shall receive the remainder.For any portion of the recovery or settlement received in connection with any suit that is initiated by Gemma and in which Passage was not a party in the litigation, any recovery in excess of litigation costs will belong to Gemma. 37â€Œâ€‹â€‹6.3.6Each Party will reasonably cooperate and assist the other in litigation proceedings instituted hereunder but at the expense of the Party who initiated the suit (unless such suit is being jointly prosecuted by the Parties). For clarity, [*]. If Gemma is subjected to Third Party discovery related to the Licensed Patent Rights or Licensed Products licensed to Passage hereunder, Passage will pay Gemmaâ€™s documented out of pocket expenses with respect to same.6.4Patent Marking.Passage shall place in a conspicuous location on any Licensed Product (or its packaging where appropriate and practicable) made or sold under this Agreement a patent notice in accordance with the Laws concerning the marking of patented articles where such Licensed Product is made or sold, as applicable.6.5Patent Term Extensions.The Parties shall reasonably cooperate with each other in obtaining patent term extensions when applicable to any Licensed Patent Right in any country or regulatory jurisdiction under any statute or regulation equivalent or similar to 35 U.S.C. Â§156. [*].Subject to the terms set forth in this Section 6.5, in each instance the non-filing Party shall abide by such election and the terms set forth herein and cooperate as reasonably requested by the other Party in connection with the foregoing (including by providing appropriate information and executing appropriate documentation). The filing Party shall provide the non-filing Party a copy of such filing in advance and will consider in good faith reasonable comments and suggestions by the non-filing Party. Passage shall ensure that all Sublicensees and Affiliates are bound by the terms and conditions set forth in this Section 6.5.Article 7â€‹CONFIDENTIALITY & PUBLICATION7.1Confidential Information.Passage shall not disclose Confidential Information (as defined below) to Gemma unless it is anticipated to be necessary or useful to the performance of any of the Research Programs or is reasonably responsive to Passageâ€™s reporting obligations under this Agreement or any other request of Gemma. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] thereafter, the receiving Party (the â€œReceiving Partyâ€) and its Affiliates will keep confidential and will not publish or otherwise disclose or use for any purpose, other than as provided for in this Agreement, any confidential or proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise), including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to the past, present and future marketing, financial, and research and development activities of any product or potential product or useful technology of the Disclosing Party or its Affiliates and the pricing thereof (collectively, â€œConfidential Informationâ€), which is disclosed to it by the other Party (the â€œDisclosing Partyâ€) or its Affiliates or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement. 38â€Œâ€‹â€‹7.2Exceptions to Confidentiality.â€œConfidential Informationâ€ does not include information that (a) was in the lawful knowledge and possession of the Receiving Party or its Affiliates prior to the time it was disclosed to, or learned by, the Receiving Party or its Affiliates, or was otherwise developed independently by the Receiving Party or its Affiliates, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party or its Affiliates; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party or its Affiliates, as evidenced by written records of the Receiving Party or its Affiliates; (c) became generally available to the public or otherwise part of the public domain after its disclosure other than through any act or omission of the Receiving Party or its Affiliates in breach of this Agreement; or (d) was disclosed to the Receiving Party or its Affiliates, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party or its Affiliates not to disclose such information to others. In the event a Receiving Party is required to make a disclosure under Law or regulation, the order of a court of competent jurisdiction, or the rules of the U.S. Securities and Exchange Commission (including by reason of any securities offering by Passage), any stock exchange or listing entity, such disclosure will not constitute a breach of this Article 7, provided such Receiving Party shall provide [*] to the Disclosing Party and take all reasonable steps to limit the extent of the disclosure and obtain confidential treatment for any remaining required disclosure.7.3Preservation of Patentability. Â â€‹In order to preserve the patentability of either Partyâ€™s intellectual property and to preserve either Partyâ€™s publication rights, each Party shall [*].7.4Publications. Each Party (the â€œPublishing Partyâ€) shall have the sole and exclusive first right to publish, publicly present or otherwise publicly disclose Research Results generated by such Party for any purpose, subject to the following provisions; provided, however, that if the other Party (the â€œnon-Publishing Partyâ€) provides written request to the Publishing Party to publish, publicly present or otherwise publicly disclose the Research Results, and the Publishing Party does not publish, publicly present or otherwise publicly disclose such Research Results within [*], the non-Publishing Party shall be entitled to publish, publicly present or otherwise publicly disclose such Research Results in accordance with the provisions of this Section 7.4. The Publishing Party shall furnish the non-Publishing Party with a copy of any proposed publication, presentation, or other public disclosure at least [*] in advance of the date of such presentation or public disclosure or the submission of said proposed publication in order for the non-Publishing Party to review and comment on said proposed publication, presentation, or other public disclosure to (a) determine whether it contains any of the non-Publishing Partyâ€™s Confidential Information and (b) enable the non-Publishing Party to identify any of the Publishing Partyâ€™s intellectual property that it wishes the Publishing Party to file patent applications on or to seek other intellectual property protection for. If within the [*] review period (i) the non-Publishing Party notifies the Publishing Party in writing that the non-Publishing Party requires deletion of the non-Publishing Partyâ€™s Confidential Information from the publication, presentation, or other disclosure, the Parties will cooperate to modify the same to ensure that the non-Publishing Partyâ€™s Confidential Information is not disclosed or (ii) if the non-Publishing Party requests in writing that publication, presentation, or other disclosure be delayed to allow for patent filings or other intellectual property protection on certain items in the proposed publication, presentation, or other disclosure, the Publishing Party shall delay the same for up to 39â€Œâ€‹â€‹[*] to allow for the filing of patent applications or other intellectual property protection. For clarity, [*]; provided, however, [*].Article 8â€‹REPRESENTATIONS, WARRANTIES AND COVENANTS8.1Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:Mutual Representations and Warranties. 8.1.1such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;8.1.2such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;8.1.3this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditorsâ€™ rights generally and by general equitable principles; and8.1.4such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement.8.2Representations and Warranties of Gemma. Gemma hereby represents and warrants to Passage that, as of the Effective Date:8.2.1Gemma has all rights, capabilities and resources necessary to conduct the Research Plans;8.2.2Gemma Controls all Licensed Patent Rights, Discovery Patent Rights and DRG Patent Rights; 8.2.3Gemma Controls all [*] that were, prior to the Effective Date, Controlled by Penn and necessary or useful to exploit the licenses granted to Passage under this Agreement; 8.2.4[*];8.2.5subject to the Specified Obligations, Gemma has neither granted nor agreed to grant, any license to the Exclusive Licensed Patent Rights in the CNS Field in the Field of Use anywhere in the world;8.2.6[*];8.2.7all data included in the Licensed Know-How and/or which has been or will be used to support the filing, prosecution or maintenance of the Licensed Patent Rights has been generated, and the Research Programs will be conducted, in a thorough and professional manner; and8.2.8[*]. 40â€Œâ€‹â€‹8.3Disclaimer of Representations and Warranties.8.3.1Other than the representations and warranties provided in Sections 8.1 and 8.2 above, GEMMA MAKES NO REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, AND EXPLICITLY DISCLAIMS ANY REPRESENTATION AND WARRANTY, INCLUDING WITH RESPECT TO ANY ACCURACY, COMPLETENESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT OR TITLE FOR THE INTELLECTUAL PROPERTY, PATENT RIGHTS, LICENSE AND ANY LICENSED PRODUCT.8.3.2Furthermore, nothing in this Agreement will be construed as:(a)A representation or warranty by Gemma as to the validity or scope of any Licensed Patent Right, Discovery Patent Right or DRG Patent Right;(b)A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;(c)Obligating Gemma to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement; and(d)Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Gemma other than Licensed Patent Rights as defined herein, regardless of whether such Patent Rights are dominant or subordinate to Licensed Patent Rights or DRG Patent Rights.8.3.3[*].8.4Covenants of Gemma. Gemma hereby covenants to Passage that:8.4.1neither Gemma nor its Affiliates will grant any option, right or license to any Third Party relating to any of the intellectual property rights it Controls (including, without limitation, the Licensed Patent Rights, Licensed Know-How, Licensed Materials, DRG Patent Rights, and DRG Know-How) with respect to any Licensed Product which conflict with the option, rights or licenses granted to Passage in the Field of Use hereunder;8.4.2subject to Gemmaâ€™s retained rights as set forth in Section 3.2, except as otherwise expressly agreed to by Passage in writing, neither Gemma nor its Affiliates will use or otherwise exploit (and neither will grant any Third Party the right to use or otherwise exploit) any Licensed Product for any purposes;8.4.3except as otherwise expressly permitted under this Agreement, Gemma will not, and will cause its Affiliates not to assign, transfer, convey, encumber (through a lien, charge, security interest, mortgage or similar encumbrance) or dispose of, or enter into any agreement with any Third Party to assign, transfer, convey, encumber (through a lien, charge, security interest, mortgage or similar encumbrance) or dispose of, any Licensed Patent Rights, Licensed Know-How, Licensed Materials, DRG Patent Rights, DRG Know-How or any Licensed Product, except to the extent that such assignment, transfer, 41â€Œâ€‹â€‹conveyance, encumbrance or disposition would not conflict with, be inconsistent with or adversely affect in any respect any of the option, rights or licenses granted to Passage hereunder;8.4.4Gemma will not breach, violate, default, or commit any act or omission that would give rise to a right of termination, renegotiation, acceleration or material change of, the terms of (collectively, â€œDefaultâ€) the Upstream License Agreement in a manner that results in or would reasonably be expected to result in, the counterparty thereto terminating the Upstream License Agreement in a manner that would diminish the scope or exclusivity of the licenses granted to Passage under any Licensed Patent Rights, Licensed Know-How, Licensed Materials, DRG Patent Rights, or DRG Know-How; provided, however, that Gemma shall not be in violation of this Section 8.4.4 in the case of any Default that results from any action or inaction of Passage or any of its Affiliates or Sublicensees;8.4.5all activities conducted by or on behalf of Gemma or its Affiliates hereunder with respect to any Licensed Product will be conducted in accordance with all applicable Laws, and in sufficient detail and in a good scientific manner appropriate for scientific, regulatory and intellectual property protection purposes, and all records kept in connection with such activities will be complete and accurate, and fully and accurately reflect all work done, data and developments made, and results achieved in the performance of the Research Programs;8.4.6if Gemma receives notice of an alleged Default by Gemma or its Affiliates under the Upstream License Agreement, where termination of the Upstream License Agreement or any diminishment of the scope or exclusivity of the licenses granted to Passage under the Licensed Patent Rights, Licensed Know-How, Licensed Materials, DRG Patent Rights, or DRG Know-How is being or could be sought by the counterparty or result from such Default, then Gemma will promptly, but in no event less than [*] thereafter, provide written notice thereof to Passage;8.4.7Gemma will not (a) modify, amend, or terminate the Upstream License Agreement or exercise, waive, release, or assign any rights or claims thereunder, in each case in a manner that would adversely affect Passageâ€™s rights or Gemmaâ€™s ability to perform its obligations under this Agreement or (b) modify or amend the Upstream License Agreement in a manner that would impose additional obligations on Passage as a sublicensee under such Â Upstream License Agreement, in each case ((a) and (b)), without first obtaining Passageâ€™s prior written consent;8.4.8all of Gemmaâ€™s employees, officers and consultants who will perform activities under this Agreement with respect to any Licensed Product or Research Program have executed or will execute agreements or have existing obligations under applicable Laws requiring assignment to Gemma of all inventions made during the course of and as the result of their association with Gemma, free from any encumbrances, and obligating the individual to maintain as confidential Gemmaâ€™s Confidential Information as well as the confidential information of other parties (including Confidential Information of Passage

and its Affiliates) which such individual may receive (it being understood that such confidentiality obligations may be general in nature and need not be specific to Confidential Information under this Agreement), in each case above, to the extent required to support Gemmaâ€™s obligations under this Agreement; 42â€Œâ€‹â€‹8.4.9without limitation of Gemmaâ€™s other obligations under this Agreement, if at any time after execution of this Agreement Gemma becomes aware that it or any employee, agent, or Approved Subcontractor of Gemma who participated, or is participating, in the performance of any activities with respect to any of the Research Programs is on, or is being added to, the list of firms or persons debarred pursuant to Section 306(a) or 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Â§ 335(a)), it will provide written notice of this to Passage within [*] of its becoming aware of this fact; and8.4.10Gemma will use commercially reasonable efforts to maintain security systems and intellectual property protection practices within its organization equivalent to international industry standards to avoid the unauthorized disclosure of intellectual property rights, including Know-How and Confidential Information of Passage, to any Third Party.8.5Covenants of Passage.8.5.1Passage and its Affiliates will not, directly or indirectly (including where such is done by a Third Party on behalf of Passage or its Affiliates, at the urging of Passage or its Affiliates or with the assistance of Passage or its Affiliates) institute or make any Challenge; provided, however, that if any Licensed Patent Right, Discovery Patent Rights, or DRG Patent Right is asserted against Passage or its Affiliate for activities authorized under this Agreement, then Passage or its Affiliates (or the Sublicensee or sub-Sublicensee) is entitled to all and any defenses available to it including challenging the validity or enforceability of such Patent Right.8.5.2Passage will comply with all Laws that apply to its activities or obligations under this Agreement. For example, Passage will comply with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Passage that Passage will not export data or commodities to certain foreign countries without prior approval of the agency.8.5.3Passage will not grant a security interest in or to any Licensed Patent Rights, Discovery Patent Rights, or DRG Patent Right.Article 9â€‹INDEMNIFICATION; INSURANCE AND LIMITATION OF LIABILITY9.1Indemnification by Passage. 9.1.1Passage shall defend, indemnify and hold Gemma, its Affiliates, and their respective directors, officers, employees, contractors and agents (the â€œGemma Indemniteesâ€) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneysâ€™ fees), including, without limitation, bodily injury, risk of bodily injury, death and property damage (collectively, â€œLossesâ€) arising out of any Third Party claim or suit (each, a â€œThird Party Claimâ€) related to: (a)the negligence, recklessness or wrongful intentional acts or omissions of Passage, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Passageâ€™s performance of its obligations or exercise of its rights under this Agreement; 43â€Œâ€‹â€‹(b)any breach of this Agreement by Passage; or(c)the Development, Manufacturing or Commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Passage or its Affiliates or Sublicensees;provided that Passageâ€™s obligations pursuant to this Section 9.1 shall not apply to the extent such Losses arise out of any conditions set forth in Sections 9.2.1(a)-(b) for which Gemma is obligated to indemnify any Passage Indemnitee under Section 9.2.9.2Indemnification by Gemma.9.2.1Gemma shall defend, indemnify and hold Passage, its Affiliates, and their respective directors, officers, employees, contractors and agents (the â€œPassage Indemniteesâ€) harmless from and against any and all Losses arising out of Third Party Claim related to:(a)the negligence, recklessness or wrongful intentional acts or omissions of Gemma, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Gemmaâ€™s performance of its obligations or exercise of its rights under this Agreement; or(b)any breach of this Agreement by Gemma;provided that Gemmaâ€™s obligations pursuant to this Section 9.2 shall not apply to the extent such Losses arise out of any conditions set forth in Sections 9.1(a)-(c) for which Passage is obligated to indemnify any Gemma Indemnitee under Section 9.1.9.3Procedure.9.3.1The Party seeking indemnification under Section 9.1 or Section 9.2 (the â€œIndemnified Partyâ€) shall inform the other Party (the â€œIndemnifying Partyâ€) of the Third Party Claim giving rise to the obligation to indemnify pursuant to such Section within [*] after receiving written notice of such Third Party Claim, it being understood and agreed, however, that the failure or delay by an Indemnified Party to timely give such notice shall not affect the indemnification provided hereunder except to the extent the Indemnifying Party is actually and materially prejudiced as a result of such failure or delay to give notice.9.3.2The Indemnifying Party shall assume and conduct the defense of the Third Party Claim using counsel of its choice; provided, however, that the Indemnified Party may participate in and monitor such defense with counsel of its choice at its own expense, subject to the Indemnifying Partyâ€™s right to control such defense. Â With respect to any Third Party Claim for which the Indemnifying Party has assumed the defense: (a) the Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Partyâ€™s expense, in connection with such defense, (b) the Indemnifying Party shall not settle any Third Party Claim without the prior written consent of the Indemnified Party if the settlement would: (i) result in or impose any obligation (including any payment obligation) on the Indemnified Party, or (ii) result in any admission of wrong-doing or fault by the Indemnified Party, and (c) so long as the Indemnifying Party is actively defending the Third Party Claim in good faith, the Indemnified Party shall not settle such Third Party Claim without the prior written consent of the Indemnifying Party. Â If the Parties cannot 44â€Œâ€‹â€‹agree as to the application of Section 9.1 or Section 9.2 to any Third Party Claim, pending resolution of the dispute pursuant to Section 11.10, the Parties may conduct separate defenses of such Third Party Claim(s), with each Party retaining the right to claim indemnification from the other Party in accordance with Section 9.1 or Section 9.2, as applicable, upon resolution of the underlying claim. Â If the Indemnifying Party does not assume and conduct the defense of the Third Party Claim as provided above, (A) the Indemnified Party may defend against and consent to the entry of any judgment, or enter into any settlement with respect to, the Third Party Claim in any manner the Indemnified Party may deem reasonably appropriate, and (B) the Indemnifying Party will remain responsible to indemnify the Indemnified Party as provided under Section 9.1 or Section 9.2. Â Notwithstanding anything to the contrary in this Section 9.3.2, in the event that Passage believes in good faith that a bona fide conflict exists between Gemma and Passage or any other Passage Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Passage or any other Passage Indemnitee shall have the right to defend against any such claim or suit itself, including by selecting its own counsel, with any reasonable attorneyâ€™s fees and litigation expenses being paid for by Gemma. Â Gemma will pay such fees and expenses either directly or will reimburse such Person within [*] after Gemmaâ€™s receipt of an invoice for such fees and expenses.9.4Insurance.9.4.1Beginning no later than commencement of the first Clinical Study for any Licensed Product, Passage, at its sole cost and expense, must insure its activities in connection with the exercise of its rights under this Agreement and obtain, and keep in force and maintain Commercial Form General Liability Insurance (contractual liability included) with limits as follows:(a)Each occurrence[*];(b)General aggregate[*]Prior to the commencement of clinical trials, if applicable, involving Licensed Product:(c)Clinical trials liability insurance[*]Prior to the First Commercial Sale of a Licensed Product:(d)Products liability insurance[*]Gemma may review periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section 9.4.1, and has the right to require Passage to adjust the limits in Gemmaâ€™s reasonable discretion.9.4.2If the above insurance is written on a claims-made form, it shall continue for [*] following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Effective Date of this Agreement.9.4.3Passage expressly understands, however, that the coverages and limits in Section 9.4.1 do not in any way limit Passageâ€™s liability or indemnification obligations. Passageâ€™s insurance will: 45â€Œâ€‹â€‹(a)Be issued by an insurance carrier with an [*] or better;(b)Provide for [*] advance written notice to Gemma of any modification;(c)State that Gemma is endorsed as an additional insured with respect to the coverages in Section 9.4.1; and(d)Include a provision that the coverages will be primary and will not participate with nor will be excess over any valid and collective insurance or program of self insurance carried or maintained by Gemma.9.4.4Passage must furnish to Gemma with (a) valid certificate of insurance evidencing compliance with all requirements of this Agreement and (b) additional insured endorsements for Passageâ€™s applicable policies naming Gemma and â€œThe Trustees of the University of Pennsylvaniaâ€ as additional insureds. Passage must furnish both documents within [*] of the Effective Date, once per year thereafter and at any time there is a modification in such insurance.9.5LIMITATION OF LIABILITY.EXCEPT FOR DAMAGES ARISING FROM A BREACH OF ARTICLE 7 OR DAMAGES ARISING FROM A PARTYâ€™S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF.Article 10â€‹TERM AND TERMINATION10.1Term.The term of this Agreement (the â€œTermâ€) shall commence on the Effective Date and, unless terminated sooner as provided below, shall continue in full force and effect on a country-by-country and Licensed Product-by-Licensed Product basis until the latest of (a) expiration of the last Valid Claim of the Licensed Patent Rights or DRG Patent Rights in such country for such Licensed Product, (b) expiration of the Royalty Period, whereupon the License to such country for such Licensed Product will become perpetual and fully paid-up, and (c) the expiration or termination of the Option Period and any Program Extension Research Terms.10.2Termination of Agreement for Convenience.Passage may, at its convenience, terminate this Agreement or terminate any Licensed Product for an Indication in the Field of Use, upon providing at least [*] prior written notice to Gemma of such intention to terminate, provided that upon termination Passage ceases using the License for making, using, or selling the affected Licensed Product(s) in all Fields of Use. 46â€Œâ€‹â€‹10.3Termination For Cause.10.3.1In the event Passage fails to achieve any Diligence Event by the corresponding Achievement Date (as the same may be extended under this Agreement in accordance with Section 5.7) and does not cure such breach within [*] written notice (or a longer period of up to [*] if the Parties mutually agree that such longer period is necessary and acceptable) to the reasonable satisfaction of Gemma, Gemma has the right and option to terminate this Agreement on an Indication-by-Indication basis for the Indication in which diligence has not been achieved, upon written notice, with immediate effect.10.3.2In addition to all other remedies available to it, Gemma may terminate this Agreement (a) on an Indication-by-Indication basis, upon at least [*] written notice, upon a failure of Passage to pay the Research Support Amount for the Research Program for such Indication when due pursuant to Section 2.3, unless Passage cures such failure within such notice period, (b) on an Indication-by-Indication basis, upon [*] written notice if Passage fails to comply with any Laws that apply to its activities or obligations under this Agreement with respect to such Indication(s), which failure(s) can be remedied, and Passage fails to remedy such lack of compliance within such [*] period, (c) in its entirety, upon written notice, with immediate effect, if Passage grants a security interest in any Licensed Patent Right, Discovery Patent Right, or DRG Patent Right, or (d) in its entirety, upon written notice, with immediate effect, if Passage breaches Section 8.5.1.10.3.3If either Party materially breaches any of its material obligations under this Agreement, the non-breaching Party may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement. If such breach is not cured within [*] after the breaching Partyâ€™s receipt of such notice (for non- payment), and [*] after such notice for all other material breaches, such termination shall become effective upon a notice of termination by the terminating Party thereafter; provided, however, [*]. In addition, [*].10.3.4Either Party may terminate this Agreement, upon written notice, with immediate effect if, at any time, the other Party is unable to pay its debts, including any debts related to exclusive sublicensees, when they come due, or files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition for the appointment of a receiver or trustee of such Party or of its assets, or if such Party proposes a written agreement of composition or extension of its debts, or if such Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within [*] after the filing thereof, or if such Party is a party to any dissolution or liquidation, or if such Party makes an assignment for the benefit of its creditors of all or substantially all its assets.10.4Effects of Termination.10.4.1Notwithstanding the termination of this Agreement, the following provisions shall survive: Sections [*]. Furthermore, where this Agreement is terminated in relation to fewer than all of the Indications or Licensed Products (as provided above), it will remain in effect as to the non-terminated Indication(s) or non-terminated Licensed Product(s).10.4.2Termination of this Agreement shall not relieve the Parties of any obligation or liability that, at the time of termination, has already accrued hereunder, or which is attributable to a period prior to the effective date of such termination. Termination of this Agreement shall 47â€Œâ€‹â€‹not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Partyâ€™s right to obtain performance of any obligation.10.4.3If this Agreement is terminated for any reason, all outstanding Sublicenses (including all Sublicense Documents for each Sublicense) not in default will be assigned by Passage to Gemma, and such assignment will be accepted by Gemma provided that such Sublicensee is required to comply with all obligations, including financial obligations, set forth in this Agreement of Passage. Each assigned Sublicense will remain in full force and effect with Gemma as the licensor or sublicensor instead of Passage, but the duties and obligations of Gemma under the assigned Sublicenses will not be greater than the duties of Gemma under this Agreement, and the rights of Gemma under the assigned Sublicenses will not be less than the rights of Gemma under this Agreement, including all financial consideration and other rights of Gemma. Gemma may, at its reasonable discretion, amend such outstanding Sublicenses to contain the terms and conditions found in this Agreement. If Gemma requests that Passage assign to Gemma all Regulatory Approvals for the Licensed Product upon termination of this Agreement by Passage under Section 10.2 or by Gemma under Section 10.3, then Passage agrees to negotiate the terms of such an assignment in good faith (it being understood that the foregoing will not preclude Passage from requiring Gemma to pay commercially reasonable consideration for such assignment). [*].10.4.4Within [*] after termination of this Agreement or any Indication (other than termination by Passage pursuant to Section 10.3.3), Passage shall pay Gemma all costs through the effective termination date per the budget of the applicable Research Plan(s) as well as all commitments related to the performance of the applicable Research Plan(s) (i.e., all costs or non-cancellable commitments incurred prior to the receipt, or issuance, by Gemma of the notice of termination and the cost of each employee to the extent supported under the Research Plan until the earlier of (a) [*] after termination of this Agreement and (b) reassignment of such employee supported under the Research Plan; and subject to Gemmaâ€™s written notification to Passage and Passageâ€™s acknowledgement of all costs and non-cancellable commitments as they arise) incurred by Gemma under this Agreement, or for the terminated Indication, as applicable.10.4.5Upon termination of this Agreement, the License immediately terminates and Passage, its Affiliates and Sublicensees will promptly cease selling the Licensed Product(s) subject to such termination. Each Party will return (or destroy, as directed by the other Party) all data, files, records and other materials containing or comprising the other Partyâ€™s Confidential Information with respect to this Agreement, except to the extent such Confidential Information is necessary or useful to conduct activities in connection with surviving portions of this Agreement. Notwithstanding the foregoing, the Parties will be permitted to retain one copy of such data, files, records, and other materials for archival and legal compliance purposes.10.4.6Upon termination of this Agreement or any Licensed Product for an Indication in the Field of Use by Passage under Section 10.2 or by Gemma under Sections 10.3 or 10.4, Passage agrees [*]. 48â€Œâ€‹â€‹Article 11â€‹ADDITIONAL PROVISIONS11.1Relationship of the Parties.Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. The Parties are independent contractors and at no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.11.2Expenses.Except as otherwise provided in this Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Agreement and to the consummation of the transactions contemplated hereby.11.3Third Party Beneficiary.The Parties agree that each Sublicensee is a third party beneficiary of this Agreement with respect to Section 10.4.3.11.4Use of Names.Neither Party nor its Affiliates (and, in the case of Passage, its Sublicensees) shall use the name, logo, seal, trademark, or service mark (including any adaptation of them) of the other Party or any of its Affiliates (and, in the case of Passage, its Sublicensees) or representatives, without the prior written consent of such other Party. Notwithstanding the foregoing, each Party may use the name of the other Party in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by such Party for the purpose of raising financing for the operations of such Party as related to Licensed Products, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Licensed Patent Rights, DRG Patent Rights, DRG Know-How and/or Licensed Know-How (subject to the provisions of Article 7) have been licensed from Gemma to Passage, and/or that such Party is collaborating with the other Party on the Research Programs, and to inform a reader of the identity and published credentials of inventors of intellectual property, and (b) any securities reports required to be filed with the Securities and Exchange Commission.11.5No Discrimination.Neither Gemma nor Passage will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.11.6Successors and Assignment.11.6.1The terms and provisions hereof shall inure to the benefit of, and be binding upon, the Parties and their respective successors and permitted assigns.11.6.2Neither Party may assign or transfer this Agreement or any of such Partyâ€™s rights or obligations created hereunder without the prior written consent of the other Party, provided that: (a) such other Party shall not unreasonably withhold, condition or delay its consent; and (b) either Party may assign this Agreement, without the otherâ€™s consent, to an Affiliate 49â€Œâ€‹â€‹of such Party or to a successor entity by way of merger, acquisition, or the sale of all or substantially all of such Partyâ€™s assets or business to which this Agreement relates; provided, that (i) the assignee shall

expressly agree in writing to be bound by such Partyâ€™s obligations and liabilities under this Agreement, and (ii) each Party shall promptly notify the other Party of any assignment or transfer under the provisions of this Section 11.6.11.6.3Any assignment not in accordance with this Section 11.6 shall be void.11.7Further Actions.Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.11.8Entire Agreement of the Parties; Amendments.This Agreement, together with the Exhibits, Appendices, or Schedules hereto, constitutes and contains the entire understanding and agreement of the Parties respecting the subject matter hereof and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party. Â 11.9Governing Law.This Agreement shall be governed by and interpreted in accordance with the laws of the Commonwealth of Pennsylvania, excluding application of any conflict of laws principles that would require application of the law of a jurisdiction outside of the Commonwealth of Pennsylvania.11.10Dispute Resolution.If a dispute arises between the Parties concerning this Agreement, then the Parties will confer, as soon as practicable, in an attempt to resolve the dispute (in accordance with the provisions of Section 2.11 as applicable); provided, however, that nothing in this Section 11.10 will prohibit either Party from (a) [*] or (b) [*]. In addition, in the event of a dispute regarding the interpretation of this Agreement, or whether a Party has committed and/or cured a material breach of this Agreement (for purposes of the other Partyâ€™s termination rights under Article 10), if the dispute is not resolved within [*] under the first sentence of this Section 11.10, then: (i) upon either Partyâ€™s request such dispute will be escalated to Passageâ€™s Chief Executive Officer and Gemmaâ€™s Chief Executive Officer, for discussion in good faith in an effort to resolve such dispute; and (ii) if such dispute remains unresolved another [*] following such escalation, then either Party shall be free to bring any action in, the state and Federal courts located in the Eastern District of Pennsylvania.11.11Notices and Deliveries.Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and directed to a Party at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party. A notice will be deemed received: if delivered personally, on the date of delivery; if mailed, five (5) days after deposit in the United States mail; if sent via courier, one (1) business day after deposit 50â€Œâ€‹â€‹with the courier service; or if sent via facsimile, upon receipt of confirmation of transmission provided that a confirming copy of such notice is sent by certified mail, postage prepaid, return receipt requested.For Gemmawith a copy to:â€‹â€‹Gemma Biotherapeutics, Inc.1831 Delancey PlacePhiladelphia, PA 19103Attention: Chief Executive OfficerMcDermott Will & Emery LLP 200 Clarendon Street, Floor 58Boston, MA 02116Attention: Brian Bunnâ€‹â€‹â€‹â€‹For Passage:with a copy to:â€‹â€‹Passage BioPassage Bio1 Commerce Square, 39th Floor 1 Commerce Square, 39th FloorPhiladelphia, PA 19103Philadelphia, PA 19103 Attention: Chief Executive OfficerAttention: General Counselâ€‹11.12Waiver.A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. Except as otherwise provided herein, all rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.11.13Severability.When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Law, but if any provision of this Agreement is held to be prohibited by or invalid under Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.11.14Interpretation.The words â€œinclude,â€ â€œincludesâ€ and â€œincludingâ€ shall be deemed to be followed by the phrase â€œwithout limitation.â€ All references herein to Articles, Sections, Schedules and Exhibits shall be deemed references to Articles and Sections of, Schedules and Exhibits to, this Agreement unless the context shall otherwise require. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with GAAP, as in effect from time to time. Unless the context otherwise requires, countries shall include territories. References to any specific Law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement Law thereto.11.15Counterparts.This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable 51â€Œâ€‹â€‹document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.[SIGNATURE PAGE FOLLOWS]â€‹â€‹ 52â€Œâ€‹â€‹IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.GEMMA BIOTHERAPEUTICS, INC.PASSAGE BIO, INC.â€‹â€‹â€‹â€‹By:/s/ Annalisa Jenkinsâ€‹ â€‹â€‹ â€‹â€‹ â€‹By:/s/ Will Chouâ€‹ â€‹â€‹ â€‹â€‹ â€‹â€‹ â€‹Name:Annalisa JenkinsName:Will Chou, M.D.Title:President â€‹Title:Chief Executive Officerâ€‹â€‹â€‹ Signature Page to Research, Collaboration & License Agreementâ€Œâ€‹â€‹Exhibit ALicensed Patent Rights Aâ€‹[*] â€Œâ€‹â€‹Exhibit BResearch Plansâ€‹[*] â€Œâ€‹â€‹Exhibit CResearch Program Budgetâ€‹[*] â€Œâ€‹â€‹Exhibit DDiscovery Patent Rightsâ€‹[*]â€‹â€‹ â€Œâ€‹â€‹Exhibit ESpecified Obligationsâ€‹[*]â€‹â€‹Exhibit FForm of SDR Reportâ€‹[*] â€‹â€‹ â€Œâ€‹â€‹Exhibit GForm of Financial Reportâ€‹[*]â€‹â€‹Exhibit HDRG Patent Rightsâ€‹[*]â€‹â€‹ â€Œâ€‹â€‹Exhibit IWilson Laboratory Gene Therapy Product Policy on Clinical Candidate Designations (effective as of September 23, 2020)â€‹[*] â€Œâ€‹â€‹Exhibit 10.6Execution VersionConfidentialâ€‹â€‹CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND IS THE TYPE THAT PASSAGE BIO, INC. TREATS AS PRIVATE OR CONFIDENTIAL.SECOND AMENDED AND RESTATEDRESEARCH, COLLABORATION & LICENSE AGREEMENTDATED AS OF July 31, 2024BY AND BETWEENTHE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA ANDPASSAGE BIO, INC.â€‹â€‹ â€Œâ€‹â€‹â€‹TABLE OF CONTENTSArticle 1 DEFINITIONSâ€Œ2Article 2 COLLABORATION PROGRAMS; GOVERNANCEâ€Œ132.1Overall Projectâ€Œ132.2[Reserved]â€Œ132.3Discovery Programâ€Œ132.4Rights to Technologies arising from Discovery Program.â€Œ142.5Licensing Exclusivityâ€Œ14Article 3 LICENSES AND OTHER RIGHTSâ€Œ143.1Grant of Licenseâ€Œ143.2Retained Rightsâ€Œ163.3U.S. Government Rightsâ€Œ173.4Grant of Sublicense by Licenseeâ€Œ173.5License for Process Patentâ€Œ183.6No Implied Licenseâ€Œ19Article 4 FINANCIAL PROVISIONSâ€Œ194.1Paymentsâ€Œ194.2Milestone Paymentsâ€Œ194.3Royaltiesâ€Œ224.4Penn Sublicense Incomeâ€Œ254.5Mode of Payment and Currencyâ€Œ254.6Royalty and Penn Sublicense Income Reportsâ€Œ264.7Late Paymentsâ€Œ274.8Default Paymentâ€Œ274.9Accountingâ€Œ274.10Books and Recordsâ€Œ274.11Auditsâ€Œ274.12Taxesâ€Œ28Article 5 CLINICAL DEVELOPMENT, REGULATORY AFFAIRS; COMMERCIALIZATIONâ€Œ285.1Development Planâ€Œ285.2Clinicalâ€Œ285.3Commercializationâ€Œ295.4Manufacturingâ€Œ295.5Regulatoryâ€Œ295.6General Diligenceâ€Œ305.7Acknowledgmentâ€Œ305.8Diligence Eventsâ€Œ305.9Progress Reportsâ€Œ31Article 6 INTELLECTUAL PROPERTYâ€Œ326.1Patent Filing Prosecution and Maintenanceâ€Œ326.2Patent Costsâ€Œ336.3Infringementâ€Œ346.4Patent Markingâ€Œ376.5Patent Term Extensionsâ€Œ37 iâ€Œâ€‹â€‹Article 7â€Œ387.1Confidential Informationâ€Œ387.2Exceptions to Confidentialityâ€Œ387.3Penn Intellectual Propertyâ€Œ387.4Publicationsâ€Œ39Article 8 REPRESENTATIONS, WARRANTIES AND COVENANTSâ€Œ398.1Mutual Representations and Warranties.â€Œ398.2Representations and Warranties of Penn.â€Œ408.3Disclaimer of Representations and Warrantiesâ€Œ408.4Covenants of Licenseeâ€Œ41Article 9 INDEMNIFICATION; INSURANCE AND LIMITATION OF LIABILITYâ€Œ429.1Indemnification by Licenseeâ€Œ429.2Insuranceâ€Œ439.3LIMITATION OF LIABILITYâ€Œ44Article 10 TERM AND TERMINATIONâ€Œ4410.1Termâ€Œ4410.2Termination of the Agreement for Convenienceâ€Œ4410.3Termination For Causeâ€Œ4410.4Effects of Terminationâ€Œ45Article 11 ADDITIONAL PROVISIONSâ€Œ4611.1Relationship of the Partiesâ€Œ4611.2Expensesâ€Œ4711.3Third Party Beneficiaryâ€Œ4711.4Use of Namesâ€Œ4711.5No Discriminationâ€Œ4711.6Successors and Assignmentâ€Œ4711.7Further Actionsâ€Œ4811.8Entire Agreement of the Parties; Amendmentsâ€Œ4811.9Governing Lawâ€Œ4811.10Dispute Resolutionâ€Œ4811.11Notices and Deliveriesâ€Œ4811.12Waiverâ€Œ4911.13Severabilityâ€Œ4911.14Interpretationâ€Œ4911.15Counterpartsâ€Œ49â€‹â€‹ iiâ€Œâ€‹â€‹UNIVERSITY OF PENNSYLVANIASECOND AMENDED AND RESTATED RESEARCH, COLLABORATION & LICENSE AGREEMENTThis Second Amended and Restated Research, Collaboration & License Agreement (this â€œAgreementâ€) is effective as of July 31, 2024 (the â€œSecond Restatement Dateâ€) by and between The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation (â€œPennâ€), and Passage Bio, Inc., a corporation organized under the laws of the state of Delaware (â€œLicenseeâ€). Penn and Licensee may be referred to herein as a â€œPartyâ€ or, collectively, as â€œPartiesâ€.RECITALS:WHEREAS, Licensee and Penn entered into an original Research, Collaboration & License Agreement on September 18, 2018 (the â€œOriginal Effective Dateâ€) (as amended prior to May 5, 2020, the â€œOriginal Agreementâ€), which was restated on May 5, 2020 (the â€œFirst Restatement Dateâ€), and which subsequently was amended on August 13, 2020, November 2, 2020, December 9, 2020, June 2, 2021, August 3, 2021, November 12, 2021, December 3, 2021, on May 11, 2022, and on November 15, 2023 Â (collectively, the â€œFirst ARCAâ€);WHEREAS, Licensee is a biopharmaceutical company with expertise in the development, manufacture and commercialization of human therapeutic products for treatment of genetic disorders.WHEREAS, Penn, through Dr. James M. Wilson and the Wilson Laboratory, have technology and expertise in the research and development of gene therapy products.WHEREAS, the programs contemplated by this Agreement are of mutual interest to Licensee and Penn and furthers the educational, scholarship and research objectives of Penn as a nonprofit, tax-exempt, educational Penn, and may benefit Licensee and Penn through the creation or discovery of new inventions and the development and commercialization of Licensed Products (as defined below).WHEREAS, in connection with such First ARCA, Penn, through the Wilson Laboratory, has developed Licensed Products on behalf of Licensee.WHEREAS, concurrently with the execution of this Agreement, Penn is entering into a business transaction with Gemma Biotherapeutics, Inc. (â€œGemmaâ€) pursuant to which, inter alia, upon closing, certain assets of the Wilson Laboratory (as defined below) will transfer from Penn to Gemma, Dr. James M. Wilson will become unavailable to oversee the performance of the outstanding Research Programs and the Wilson Laboratory will no longer exist at Penn (such transaction, the â€œGemma Transactionâ€).WHEREAS, in connection with the Gemma Transaction, Penn and Gemma are entering into that certain license agreement of even date herewith, pursuant to which, inter alia, Penn and Gemma may enter into a second license agreement (collectively, the â€œGemma Licenseâ€).WHEREAS, concurrently with the execution of this Agreement, Licensee and Gemma are entering into (a) that certain Exclusive License Agreement, pursuant to which Licensee will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for GLB1 Deficiency, for GM1 gangliosidosis-1 and MPS IV, (b) that certain Exclusive License Agreement, pursuant to which Licensee will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for Krabbe disease (globoid cell leukodystrophy), and (c) that certain Exclusive License â€Œâ€‹â€‹Agreement, pursuant to which Licensee will grant to Gemma a license under certain intellectual property rights relating to the development, manufacture and commercialization of certain products for Metachromatic leukodystrophy (collectively, the â€œGemma Sublicense Agreementsâ€).WHEREAS, in connection with the Gemma Transaction, the Parties desire to amend and restate the First ARCA as of the Second Restatement Date to reflect, inter alia, the termination of the Discovery Program and all of Licenseeâ€™s funding obligations related thereto, the termination or transfer to Gemma of all outstanding Research Programs and all of Licenseeâ€™s ongoing funding obligations related thereto and the reversion to Penn of certain rights to certain technology, all as further set forth herein. NOW, THEREFORE, in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:Article 1â€‹DEFINITIONSUnless otherwise specifically provided herein, the following terms shall have the following meanings:1.1â€œAAVâ€ means adeno-associated virus.1.2â€œAchievement Dateâ€ means with respect to a Diligence Event, the corresponding date such Diligence Event is to be achieved as provided in Section 5.8 below.1.3â€œAffiliateâ€ means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.3, the word â€œcontrolâ€ (including, with correlative meaning, the terms â€œcontrolled byâ€ or â€œunder common control withâ€) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person, whether by the ownership of more than fifty percent (50%) of the voting stock of such Person, or by contract or otherwise.1.4â€œBLAâ€ means (a) a biologics license application as that term is used in defined in the PHS Act and the regulations promulgated thereunder, (b) a marketing authorization application in the European Union, or (c) any equivalent or comparable application, registration or certification in any other country or region.1.5â€œCalendar Quarterâ€ mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31 of each Calendar Year.1.6â€œCalendar Yearâ€ means each successive period of twelve (12) months commencing on January 1 and ending on December 31.1.7â€œcGMPâ€ means those current practices, as amended from time to time, related to the manufacture of pharmaceutical products and any precursors thereto promulgated in guidelines and regulations of standard compilations including the GMP Rules of the World Health Organization, the United States Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (established by the United States Department of Health and Human Services), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical products, and equivalent guidelines, regulations and standards in the Territory, as such guidelines, regulations and standards may be amended from time to time. 2â€Œâ€‹â€‹1.8â€œChallengeâ€ means that a Licensee or a Sublicensee (including sub-Sublicensees) will be deemed to have made a â€œChallengeâ€ of the Penn Patent Rights, Discovery Patent Rights or a DRG Patent Right if Licensee or such Sublicensee (including sub-Sublicensees), respectively: (a) institutes or voluntarily joins as a party to, or causes its counsel to institute on Licenseeâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, any interference, opposition, re-examination, post-grant review or similar proceeding with respect to any Penn Patent Right, Discovery Patent Right or a DRG Patent Right with the U.S. Patent and Trademark Office or any foreign patent office; or (b) makes any filing or institutes or voluntarily joins as a party to any legal proceeding, or causes its counsel to make any filing or institute or voluntarily join as a party to any legal proceeding on Licenseeâ€™s or such Sublicenseeâ€™s (including sub-Sublicensees) behalf, with a court or other Governmental Body (including, without limitation, the U.S. Patent and Trademark Office or any foreign patent office) having authority to determine the validity, enforceability or scope of the Penn Patent Rights, Discovery Patent Rights or a DRG Patent Right, in which one or more claims or allegations challenges the validity or enforceability of any Penn Patent Right, Discovery Patent Right or a DRG Patent Right.1.9â€œClinical Studyâ€ means a Phase 1 Study, Phase 1/2 Study, Phase 2 Study, or Phase 3 Study, or such other study in humans that is conducted in accordance with good clinical practices and is designed to generate data in support or maintenance of an application for Regulatory Approval.1.10â€œCNS Fieldâ€ means the field of CNS Monogenic Rare Disorders. For clarity, (a) [*], and (b) [*]. For further clarity, [*]. For further clarity, [*]. 1.11â€œCNS Monogenic Rare Disorderâ€ means a rare disease or condition (as determined in accordance with Sec. 526 of the FD&C Act or corresponding Laws outside the United States) with significant morbidity in the central nervous system (â€œCNSâ€) or peripheral nervous system (â€œPNSâ€) [*]. For further clarity, [*].1.12â€œCombination Productâ€ means a Licensed Product that is delivered with one or more additional active ingredients and/or other items or services incident to the administration of any such Licensed Product (with or without one or more such other active ingredients), [*], in each such case when any of the foregoing are co-formulated, co-packaged or sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).1.13â€œCommercially Reasonable Effortsâ€ means the efforts and resources that a similarly situated biotechnology company would use for its own internally discovered technology of similar commercial potential and similar stage of development, taking into account the likely timing of the technologyâ€™s entry into the market and any patent and other proprietary position, safety and efficacy, product profile, the then-current competitive and regulatory environments for the product. Without limiting the foregoing, Commercially Reasonable Efforts requires, with respect to such obligations, that the Party (a) promptly assign responsibility for such obligation to specific employee(s) who are accountable for progress and monitor such progress on an on-going basis, (b) set annual objectives for carrying out such obligations, and (c) allocate resources designed to advance progress with respect to such objectives.1.14â€œCompleted Research Programâ€ means [*].1.15â€œCompulsory Licenseâ€ means a compulsory license under Penn Patent Rights obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in any country. For clarity, [*]. 3â€Œâ€‹â€‹1.16â€œControlledâ€ means, with respect to intellectual property rights, that a Party or one of its Affiliates owns or has a license or sublicense to such intellectual property rights and has the ability to provide, grant a license or sublicense to, or assign its right, title and interest in and to, such intellectual property rights as provided for in the Agreement without (a) violating the terms of any other agreement or other arrangement with any Third Party from whom the Party or its Affiliate acquired such intellectual property rights, (b) requiring additional obligations, liabilities or financial consideration to such Third Party in connection with the grant of such license or sublicense (other than consideration for which Licensee agrees to bear the entire cost), or (c) violating the terms of, or requiring additional obligations, liabilities or financial consideration to a Third Party under, [*].1.17â€œDevelopment Transition Pointâ€ or â€œDTPâ€ means on a Licensed Product-by-Licensed Product basis the date on which the IND-enabling studies for such Licensed Product under the applicable Completed Research Program have been completed and immediately prior to filing of the IND, unless otherwise agreed by the Parties.1.18â€œDiligence Eventâ€ means each of the events that Licensee, itself or

through any of its Affiliates or Sublicensees, is expected to accomplish in the development of each Licensed Product in each Indication set forth in Section 5.8. 1.19â€œDiscovery Patent Rightsâ€ means [*]. For clarity, [*]. 1.20â€œDiscovery Programâ€ means the discovery research program conducted at Penn solely by the Wilson Laboratory during the Discovery Term, which program consisted of the Discovery Tasks.1.21â€œDiscovery Tasksâ€ means (a) [*], (b) [*], (c) [*], (d) [*], (e) [*], and (f) [*]. For clarity, [*].1.22â€œDiscovery Termâ€ means the period that commenced on [*], and expires on [*]. 1.23â€œDRG Excluded Indicationsâ€ means [*].1.24â€œDRG Know-Howâ€ means all Know-How related to DRG Technology that is Controlled by Penn and (a) [*] or (b) [*], and in each case (a) and (b) [*]. 1.25â€œDRG Patent Rightsâ€ means the Patent Rights [*] and (a) [*], and (b) [*], and (c) [*].1.26â€œDRG Technologyâ€ means [*].1.27â€œEMAâ€ means the European Medicines Agency and any successor entity thereto.1.28â€œFD&C Actâ€ means the United States Federal Food, Drug and Cosmetic Act, as amended.1.29â€œFDAâ€ means the United States Food and Drug Administration and any successor entity thereto.1.30â€œField of Useâ€ means prophylactic, diagnostic and therapeutic uses in humans. For clarity, [*].1.31â€œFIHâ€ means on a Licensed Product-by-Licensed Product basis, a first in human Clinical Study for a Licensed Product.1.32â€œFirst Commercial Saleâ€ means, on a country-by-country basis, the first commercial transfer or disposition for value of Licensed Product in such country to a Third Party by Licensee, or any of its Affiliates or Sublicensees, in each case, after Regulatory Approvals have been obtained for such country. 4â€Œâ€‹â€‹1.33â€œFPFDâ€ means, on a Licensed Product-by-Licensed Product basis with respect to each Clinical Study, the first dosing of the first patient in such Clinical Study.1.34â€œGAAPâ€ means United States generally accepted accounting principles applied on a consistent basis.1.35â€œGene Therapy Productâ€ means a pharmaceutical product (or proposed or prospective pharmaceutical product) that inserts one or more functional genes or proteins into a patientâ€™s CNS or PNS cells using a parvovirus vector, including but not limited to an AAV. For clarity, Gene Therapy Products [*]. For clarity, [*].1.36â€œGeneric Productâ€ means, with respect to a particular Licensed Product in a country, a generic or biosimilar pharmaceutical product, that is not produced, licensed or owned by Licensee, any of its Affiliates or Sublicensees, that: (a) is bioequivalent or biosimilar to such Licensed Product; and (b) is approved for use in such country by a Regulatory Authority by referencing the prior approval, in whole or part, or safety and efficacy data submitted in support of the prior approval, of the Licensed Product. Generic Product includes, but is not limited to, any pharmaceutical products for which Regulatory Approval is obtained via: (i) a bioequivalence or bioavailability showing such as those covered by section 505(j) of the FD&C Act or an equivalent outside the United States; or (ii) a biosimilarity or interchangeability determination such as those covered by section 351(k) of the PHS Act or an equivalent outside the United States.1.37â€œGovernmental Bodyâ€ means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, provincial, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.1.38â€œINDâ€ means an Investigational New Drug Application as defined in the FD&C Act and the regulations promulgated thereunder, or the equivalent application to the equivalent Regulatory Authority in any other regulatory jurisdiction, including a Clinical Trial Authorization to the European Medicines Agency, the filing of which is necessary to initiate or conduct clinical testing of a pharmaceutical product in humans in such jurisdiction.1.39â€œIND Clearanceâ€ means on a Licensed Product-by-Licensed Product basis the date on which the IND-enabling studies for such Licensed Product under the applicable Completed Research Program have been completed, Licensee has filed the IND with a Regulatory Authority, and such Regulatory Authority has cleared such IND as safe to proceed.1.40â€œIndicationâ€ means each of the following indications for a Gene Therapy Product: (a) Krabbe disease (globoid cell leukodystrophy) (â€œKrabbeâ€) through parvovirus vector delivery of nucleic acid polymers for expression of galactosylceramidase, (b) Metachromatic leukodystrophy (â€œMLDâ€) through parvovirus vector delivery of nucleic acid polymers for expression of arylsulfatase A, (c) galactosidase deficiency (â€œGLB1 Deficiencyâ€), for GM1 gangliosidosis-1 and mucopolysaccharidosis type IV (â€œMPS IVâ€) through parvovirus vector delivery of nucleic acid polymers for expression of GLB1, and (d) Frontotemporal dementia (â€œFTDâ€) through parvovirus vector delivery of nucleic acid polymers for expression of progranulin (collectively, the 5â€Œâ€‹â€‹â€œIndicationsâ€). Pursuant to Section 3.1.1(d), the indications for PBFT02 have been expanded as noted in that certain letter to Penn dated December 20, 2023; provided, however, that such indications shall not constitute â€œIndicationsâ€ for purposes of Section 2.5 of this Agreement.1.41â€œKnow-Howâ€ means intellectual property, data, results, pre-clinical and clinical protocols and study data, chemical structures, chemical sequences, information, inventions, formulas, techniques, methods, processes, procedures and developments. â€œKnow-Howâ€ does not include Penn Patent Rights, Discovery Patent Rights or DRG Patent Rights claiming any of the foregoing. â€œKnow- Howâ€ also does not include Licensed Materials.1.42â€œLawâ€ or â€œLawsâ€ means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.1.43â€œLicensed Know-Howâ€ means all Know-How that is Controlled by Penn and (a) developed by the Wilson Laboratory as of the Original Effective Date, or (b) developed or discovered in the Wilson Laboratory under the Discovery Program or any of the Research Programs (including but not limited to all Research Results), and, in each case (a) and (b), is necessary or reasonably useful to develop, make, use, sell, offer for sale or import a Licensed Product in the Field of Use. 1.44â€œLicensed Materialâ€ means biological or chemical materials that are Controlled by Penn and available from the Wilson Laboratory at Penn and necessary or useful to exploit the licenses granted to Licensee under the Agreement, to the extent that Penn was (as of the Original Effective Date or at any relevant time during the Discovery Term) able to grant rights to such materials to Licensee. Such biological and chemical materials include cell lines, viral seed stocks, product- specific reference materials, platform or product specific assay controls and reagents that are not available as standard commercial items. 1.45â€œLicensed Productâ€ means any (a) process, service or method covered by a Valid Claim or whose use or practice would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim, or would infringe a Valid Claim once issued (â€œMethodâ€); (b) article, composition, apparatus, substance, chemical or any other material covered by a Valid Claim or whose manufacture, import, use, offer for sale or sale would, absent the License, constitute an infringement, inducement of infringement or contributory infringement of any Valid Claim or would infringe a Valid Claim once issued; (c) service, article, composition, apparatus, chemical, substance or any other material made, used or sold by or utilizing or practicing a Method; or (d) any product that incorporates or makes use or is made through use of Licensed Know-How. For clarity, [*].1.46â€œMajor Marketsâ€ means the United States, Japan, France, Germany, Spain, Italy and the United Kingdom.1.47â€œManufacturing Patent Rightsâ€ means (a) the Patent Rights Controlled by Penn [*], (b) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, but excluding continuations-in-part except to the extent of claims entirely supported in the specification and entitled to the priority date of the parent application, and (c) any corresponding foreign Patent Rights to the foregoing. 1.48â€œMHLWâ€ means the Ministry of Health, Labor and Welfare of Japan. 6â€Œâ€‹â€‹1.49â€œNet Salesâ€ means the gross consideration invoiced or received by Licensee or any of its Affiliates or Sublicensees (including all sub-Sublicensees) for Sales of Licensed Product (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary:(a)trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds;(b)allowances or credits actually granted upon claims, returns or rejections of products; (c)charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the Sale, transportation, delivery or return of such Licensed Product;(d)customs duties, sales, excise and use taxes actually paid in connection with the transportation, distribution, use or Sale of such Licensed Product (but excluding what is commonly known as income taxes); and(e)bad debt expense and amounts actually written off by reason of uncollectible debt not to exceed [*] of the Net Sales of Licensed Product.Even if there is overlap between any of deductions described above, each individual item shall only be deducted once in the overall Net Sales calculation.In the case of a Combination Product, the Parties shall negotiate in good faith, at the latest [*] before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, as the case may be, based on the fair market value of such components for the purposes of determining a product-specific allocation of such Net Sales. Payments related to such Combination Product under this Agreement, including Royalties, Development Milestone Payments and Commercial Milestone Payments, will be calculated, due and payable based only on the portion of such Net Sales so allocated to the Licensed Product components.In case of disagreement and failure by the Parties to agree upon an allocation of Net Sales of such Combination Product to the respective Licensed Product components and other component(s) thereof, [*].1.50â€œPatent Rightsâ€ means (a) patents and patent applications, together with any unlisted patents and patent applications claiming priority thereto, and any continuations, continuations-in-part, reissues, reexamination certificates, substitutions, divisionals, supplementary protection certificates, renewals, registrations, extensions including all confirmations, revalidations, patents of addition, PCTs, and pediatric exclusivity periods and all foreign counterparts thereof, and any patents issued or issuing with respect to any of the foregoing and (b) all official correspondence relating to the foregoing.1.51â€œPenn Patent Rightsâ€ means Penn Patent Rights A, Penn Patent Rights B, and Manufacturing Patent Rights, collectively.1.52â€œPenn Patent Rights Aâ€ means (a) the Patent Rights listed in Exhibit A, (b) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, and 7â€Œâ€‹â€‹further including continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to any of the Research Programs), (c) Pennâ€™s interest in and to any jointly owned Patent Rights of the kind described in Section 2.2.4 of the First ARCA, and (d) any corresponding foreign Patent Rights to the foregoing.1.53â€œPenn Patent Rights Bâ€ means (a) the [*], (b) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, and further including continuations-in-part (to the extent related directly to the subject matter of the parent application or containing new information developed pursuant to any of the Research Programs), and (c) any corresponding foreign Patent Rights to the foregoing. For clarity, [*]. 1.54â€œPersonâ€ means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.1.55â€œPhase 1 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. Â§312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. The drug candidate can be administered to patients as a single agent or in combination with other investigational or marketed agents.1.56â€œPhase 1/2 Studyâ€ means a clinical study of a drug candidate in diseased human patients that satisfies the requirements of a Phase 1 Study and a Phase 2 Study.1.57â€œPhase 2 Studyâ€ means a clinical study of a drug candidate in human patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. Â§312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. Â§312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. Â§312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Study (e.g., a phase 1/2 trial). The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.58â€œPhase 3 Studyâ€ means a clinical study of a drug candidate in human patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States. The relevant drug candidate may be administered to patients as a single agent or in combination with other investigational or marketed agents.1.59â€œPHS Actâ€ means the United States Public Health Service Act, as amended.1.60â€œRegulatory Approvalâ€ means, with respect to a product in any regulatory jurisdiction, approval from the applicable Regulatory Authority sufficient for the manufacture, distribution, use, marketing and sale of such pharmaceutical product in such jurisdiction in accordance with Laws. â€œRegulatory Approvalâ€ does not include authorization by a Regulatory Authority to conduct named patient, compassionate use or other similar activities. 8â€Œâ€‹â€‹1.61â€œRegulatory Authorityâ€ means any Governmental Body, including the FDA, EMA or MHLW, or any successor agency thereto, that has responsibility for granting any licenses or approvals or granting pricing or reimbursement approvals necessary for the marketing and sale of a pharmaceutical product in any country.1.62â€œResearch Programâ€ means the pre-clinical discovery, research, and/or development program of Licensed Products in the Field of Use for each of the Indications funded by Licensee and conducted by the Parties under the Original Agreement or the First ARCA (collectively, all such Research Programs, the â€œResearch Programsâ€). For purposes of this Agreement, Research Programs means, collectively, [*].1.63â€œResearch Resultsâ€ means all any and all ideas, information, inventions, developments, animate and inanimate materials, including live animals, discoveries, software, Know-How, methods, techniques, formulae, data, software, processes, methodologies, techniques, biological materials, software and works of authorship, whether patentable or copyrightable, that are first conceived, discovered, developed, reduced to practice, or generated in the performance of the Research Programs or [*] by the Wilson Laboratory, including any unpatentable inventions discovered, developed or conceived in the conduct of any of the Research Programs or [*]. Research Results expressly excludes Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights.1.64â€œSaleâ€ means any transaction for which consideration is received or invoiced by Licensee, its Affiliates or Sublicensees for sale, use, lease, transfer or other disposition of a Licensed Product to or for the benefit of a Third Party. For clarity, sale, use, lease, transfer or other disposition of a Licensed Product by Licensee or any of its Affiliates or Sublicensees to another of these entities for resale (or other disposition) by such entity to a Third Party shall not be deemed a Sale.1.65â€œService Center Coresâ€ means the following core laboratories at Penn that report directly to Dr. James M. Wilson: [*].1.66â€œSpecified Licensed Productâ€ means a Licensed Product set forth on Exhibit I. 1.67â€œSpecified Obligationsâ€ means the licenses, options, and obligations that Penn has granted or owes to a Third Party that are identified in Exhibit D, [*].1.68â€œSpecified Sublicenseeâ€ means Gemma and each of its sublicensees under each of the Gemma Sublicense Agreements, and their respective successors and assigns under the Gemma Sublicense Agreements, as applicable.1.69â€œSublicense Documentsâ€ means any and all agreements, amendments or written understandings entered into with a Sublicensee (including any of its Affiliates) that are directly or indirectly related to a Sublicense, Penn Patent Rights or Licensed Product. For clarity, a development agreement or distribution agreement for a Licensed Product is a Sublicense Document.1.70â€œSublicenseeâ€ means a Person (including any Affiliate) to which a Sublicense is granted pursuant to the terms of Section 3.4.1.71â€œSublicense Incomeâ€ means income received by Licensee or its Affiliates in consideration for a Sublicense or for a grant of the right to negotiate or obtain a Sublicense, subject to the exclusions below. Sublicense Income includes such income received from a Sublicensee in the form of license issue fees, milestone payments and the like but specifically excludes (a) [*], (b) [*], (c) [*], (d) [*], or (e) [*]. 9â€Œâ€‹â€‹1.72â€œTaxâ€ means all taxes, duties, fees, premiums, assessments, imposts, levies, rates, withholdings, dues, government contributions and other charges of any kind whatsoever, whether direct or indirect, together with all interest, penalties, fines, additions to tax or other additional amounts, imposed by any Governmental Body.1.73â€œThird Partyâ€ means any Person other than Penn, Licensee or any of their respective Affiliates.1.74â€œTransferred Research Programâ€ means each of the Research Programs for Huntingtonâ€™s disease and Temporal Lobe Epilepsy, both of which have been transferred from Penn to Gemma on the Second Restatement Date, in connection with the Gemma Transaction.1.75â€œUnited Statesâ€ or â€œUSâ€ means the United States of America, its territories and possessions.1.76â€œUSDâ€ or â€œ$â€ means US dollars.1.77â€œValid Claimâ€ means a claim of (a) an issued and unexpired patent in Penn Patent Rights which claim has not been revoked or held unenforceable or invalid by a decision of a court of governmental agency of competent jurisdiction from which no further appeal can be taken or has been taken within the time allowed for appeal, and has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer; or (b) a pending patent application (that has been pending for no more than [*] from the filing date of such application) that is included in Penn Patent Rights which was filed and is being prosecuted in good faith, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.1.78â€œWilson Laboratoryâ€ means Dr. James M. Wilson and all individuals [*].1.79Other Terms. The definition of each of the following terms is set forth in the section of the Agreement indicated below:Defined TermSectionAdvance Payment6.2.3AgreementIntroductory ClauseCNS1.11Commercial Milestone4.2.2(a)Commercial Milestone Payment4.2.2(a)Confidential Information7.1Development Milestone4.2.1(a)Development Milestone Payment4.2.1(a)Disclosing Party7.1DRG1.26DRG Election Notice6.2.5DRG License3.1.2Exclusive Penn Patent Rights6.3.2Financial Report4.6First ARCARecitalsFirst Restatement DateRecitalsFTD1.40FTD Specified Licensed ProductExhibit IGemmaRecitals 10â€Œâ€‹â€‹Defined TermSectionGemma LicenseRecitalsGemma Sublicense AgreementsRecitalsGemma TransactionRecitalsGLB1 Deficiency1.40Historic Patent Costs6.2.1Infringement

Notice6.3.1Krabbe1.40License3.1.1LicenseeIntroductory ClauseLicensee Gemma AgreementRecitalsLicense Maintenance Fee4.1.1Licensing Exclusivity Period2.5Method1.45MLD1.40MPS IV1.40Ongoing Patent Costs6.2.2Original AgreementRecitalsOriginal Effective DateRecitalsParty or PartiesIntroductory ClausePatent Costs6.2.1Patent Counsel6.1.1PennIntroductory ClausePenn Indemnitees9.1.1Penn Sublicense Income4.4.1PNS1.11Product Specific Patent Rights6.1.1Progress Report5.9.1Prosecution Request6.1.2Receiving Party7.1Royalty4.3.1(a)Royalty Period4.3.2SDR Report3.4.4Second Restatement DateIntroductory Clause[*]6.1.3Sublicense3.4.1Term10.1[*]6.1.3Transaction Documents11.8â€‹Article 2â€‹COLLABORATION PROGRAMS; GOVERNANCE2.1Overall Project.Under the Original Agreement and the First ARCA, the Parties collaborated with respect to the pre-clinical development of the Specified Licensed Products, in each Indication within the Field of Use. Under this Agreement, Licensee is responsible for regulatory strategy and operations, clinical development, cGMP manufacture, and commercialization of all Licensed Products. 11â€Œâ€‹â€‹2.2[Reserved] 2.3Discovery Program2.3.1The Discovery Program commenced on [*], and terminated on July 31, 2024. Upon payment in full of the amounts set forth in Section 4.1.3, the Parties acknowledge and agree that any funding or other amounts associated with the Discovery Program due or payable by Licensee to Penn in connection with the Discovery Program have been paid, and that Licensee is under no further funding or payment obligations with respect to the Discovery Program, except for Patent Costs for Discovery Patent Rights. 2.3.2Penn shall maintain records of the results of the Discovery Program in sufficient detail and in good scientific manner appropriate for patent purposes to properly reflect all work done and results achieved. Within [*] after the expiration of the Discovery Term, Penn will provide to Licensee task-based, scientific reports of the progress and results of the Discovery Program. [*], upon Licenseeâ€™s reasonable request and at Licenseeâ€™s cost and expense, Penn will disclose and deliver Research Results from the Discovery Program to Licensee, and will use commercially reasonable efforts to provide Licensee with such reasonable additional information (to the extent such information is within Pennâ€™s possession or control) and technical assistance (to the extent individuals with the relevant expertise capable of providing such technical assistance remain at Penn) as may be reasonably needed for Licensee to interpret and use such Research Results from the Discovery Program. Notwithstanding the foregoing, [*], upon Licenseeâ€™s reasonable request and at Licenseeâ€™s cost and expense, Penn will use commercially reasonable efforts to identify and require any former employees of the Wilson Lab who were directly involved in the Discovery Program and have remained at Penn to locate and make available to Licensee such reasonable additional information (to the extent such information is within Pennâ€™s possession or control) as may be reasonably needed for Licensee to interpret and use such Research Results from the Discovery Program. Penn shall maintain records of the use of the funds provided by Licensee and shall make such records available to Licensee upon reasonable notice during Pennâ€™s normal business hours, but not more frequently than each anniversary of the First Restatement Date. All Research Results shall be solely and exclusively owned by Penn.2.4Rights to Technologies arising from Discovery Program.In the event that within [*] following the Second Restatement Date, a Discovery Patent Right is determined to be useful or necessary for a Specified Licensed Product for an Indication, Exhibit B shall be amended upon Pennâ€™s receipt of Licenseeâ€™s request, which request shall specify the additional Penn Patent Rights B that cover the applicable Specified Licensed Product for such Indication. 2.5Licensing Exclusivity.Subject to Pennâ€™s retained rights in Section 3.2, Penn shall not license, or grant any other rights in or to, any Patent Rights conceived and reduced to practice by the Wilson Laboratory during the Discovery Term in the conduct of the Discovery Program or a Research Program to another Third Party for an Indication that was the subject of a Completed Research Program for a period of the greater of (i) [*] from Pennâ€™s initiation of work under the Research Program for such Indication and (ii) [*] from IND Clearance for such Indication (â€œLicensing Exclusivity Periodâ€). At the conclusion of the Licensing Exclusivity Period for a particular Indication, [*]. Furthermore, [*]. Â 12â€Œâ€‹â€‹Article 3â€‹LICENSES AND OTHER RIGHTS3.1Grant of License.3.1.1Subject to the terms and conditions of this Agreement, Penn hereby grants to Licensee the following (collectively, the â€œLicenseâ€):(a)an exclusive, worldwide, Royalty-bearing right and license (with the right to sublicense through multiple tiers, subject to the provisions of Section 3.4), under (i) Penn Patent Rights A to make, have made, use, sell, offer for sale and import Licensed Products for the Indications ([*]), in the Field of Use during the Term), and (ii) Penn Patent Rights B to make, have made, use, sell, offer for sale and import Specified Licensed Products for the Indications [*] in the Field of Use during the Term; for clarity, [*];(b)a non-exclusive, world-wide Royalty-bearing right and license [*], under Licensed Know-How and Licensed Materials (and Pennâ€™s intellectual property rights therein) to use and practice the same in order to make, have made, use, sell, offer for sale and import Licensed Products for the Indications ([*]) in the Field of Use during the Term; and(c)a non-exclusive, worldwide, Royalty-bearing right and license under Penn Patent Rights B and Manufacturing Patent Rights, [*], to make, have made, use, sell, offer for sale and import Licensed Products for the Indications (and, if applicable, to the extent provided in Section 3.1.1(d), for other indications in the CNS Field and/or, in the case of Specified Licensed Products, outside the CNS Field) in the Field of Use during the Term, provided that for Manufacturing Patent Rights, such license applies only to Specified Licensed Products for the Indications ([*]), in the Field of Use.(d)The licenses set forth in subsections (a) through (c) above, for each of the Specified Licensed Products, are hereby automatically expanded to all indications within the CNS Field. Â Furthermore, to the extent that Licensee desires to have the License cover one or more additional indications for any Specified Licensed Product (other than the named Indication for such Specified Licensed Product) outside the CNS Field for the Field of Use during the Term, then Licensee shall provide written notice to Penn (for clarity there shall be no limit on the number of the notices that Licensee may provide pursuant to this sentence). Such additional indication will thereupon automatically be covered by the License (for such Specified Licensed Product) to the extent: (i) [*], and (ii) [*]. If the condition in the preceding clause (i) is not satisfied, Penn will inform Licensee whether [*] and if so, the Parties shall, if requested by Licensee, discuss and negotiate in good faith for the inclusion of such additional indication in the License for such Specified Licensed Product [*]. (e)Without limiting the foregoing, Penn will not license or grant any other rights in or to, any Penn Patent Rights, Licensed Know-How, DRG Patent Rights or DRG Know-How to any Third Party for any Specified Licensed Product under this Agreement for any indication in the Field of Use. 13â€Œâ€‹â€‹3.1.2Subject to the terms and conditions of this Agreement, Penn hereby grants to Licensee the following license to the DRG Technology [*]:(a)a non-exclusive, worldwide, royalty-bearing right and license ([*]), under DRG Patent Rights to make, have made, use, sell, offer for sale and import [*] for the Indications in the Field of Use during the Term; and(b)a non-exclusive, worldwide, Royalty-bearing right and license ([*]), under DRG Know-How to make, have made, use, sell, offer for sale and import [*] for the Indications in the Field of Use during the Term.3.1.3Notwithstanding anything to the contrary, to the extent the License with respect to a Licensed Product is expanded to additional indications as set forth in Section 3.1.1(d), the [*] will automatically be expanded to the same indications other than the DRG Excluded Indications; provided that the exclusion of the DRG Excluded Indications from such the [*] only apply for so long as such DRG Excluded Indications are exclusively licensed from Penn to a Third Party, and upon the termination or expiration of such exclusive license from Penn to such Third Party for any such DRG Excluded Indication, the [*] will automatically be expanded to include such DRG Excluded Indication. 3.2Retained Rights.Notwithstanding the License, Penn retains the right under Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights to: (a) conduct educational, research, clinical activities and patient care activities itself, including, but not limited to sponsored research, and (b) authorize non-commercial Third Parties to conduct educational, research and clinical activities and patient care activities; [*].3.3U.S. Government Rights.The License is expressly subject to all applicable provisions of any license to the United States Government executed by Penn and is subject to any overriding obligations to the United States Federal Government under 35 U.S.C. Â§Â§200-212, applicable governmental implementing regulations, and the U.S. Government sponsored research agreement or other guidelines, including that products that result from intellectual property funded by the United States Federal Government that are sold in the United States be substantially manufactured in the United States.3.4Grant of Sublicense by Licensee.3.4.1Penn grants to Licensee the right to grant sublicenses, in whole or in part, under the License (each, a â€œSublicenseâ€) subject to the terms and conditions of this Agreement and specifically this Section 3.4. The term â€œSublicenseâ€ shall include any grant of rights under the License by a Sublicensee to any downstream Third Party, such downstream Third Party shall also be considered a Sublicensee for purposes of this Agreement.3.4.2All Sublicenses will (i) be issued in writing, (ii) to the extent applicable, include all of the rights of Penn and require the performance of obligations due to Penn (and, if applicable, the U.S. Government under 35 U.S.C. Â§Â§200-212) contained in this Agreement and (iii) include no less than the following terms and conditions: 14â€Œâ€‹â€‹(a)Reasonable record keeping, audit and reporting obligations sufficient to enable Licensee and Penn to reasonably verify the payments due to Licensee and Penn under such Sublicense and to reasonably monitor such Sublicenseeâ€™s progress in developing and/or commercializing Licensed Product, provided that such obligations shall be no less stringent that those provided in this Agreement for Licensee.(b)Infringement and enforcement provisions that do not conflict with the restrictions and procedural requirements imposed on Licensee and do not provide greater rights to Sublicensee than as provided in Section 6.3.(c)Confidentiality provisions with respect to Confidential Information of Penn consistent with the restrictions on Licensee in Article 7 of this Agreement.(d)Covenants by Sublicensee that are equivalent to those made by Licensee in SectionÂ 8.4.(e)A requirement of indemnification of Penn by Sublicensee that is equivalent to the indemnification of Penn by Licensee under Section 9.1 of this Agreement.(f)A requirement of obtaining and maintaining insurance by Sublicensee that is equivalent to the insurance requirements of Licensee under Section 9.2 of this Agreement, including coverage under such insurance of Penn as provided in Section 9.2.(g)Restriction on use of Pennâ€™s names etc. consistent with Section 11.4 of this Agreement.(h)A requirement of antidiscrimination by Sublicensee no less stringent than that provided in Section 11.5 of this Agreement.(i)A requirement that Penn is a third party beneficiary of such Sublicense.Any Sublicense that does not include all of the terms and conditions set forth in this SectionÂ 3.4.2 or which is not issued in accordance with the terms and conditions set forth in this Section 3.4, shall be considered null and void with no further notice from Penn unless separately approved by Penn in writing. Â 3.4.3Within [*] after the execution of a Sublicense Document, Licensee shall provide a complete and accurate copy of such Sublicense Document to Penn, in the English Language. Pennâ€™s receipt of a Sublicense Document, however, will constitute neither an approval nor disapproval of the Sublicense Document nor a waiver of any right of Penn or obligation of Licensee under this Agreement.3.4.4Licensee shall provide an annual Sublicense Development Report on or before December 1 of each year during the Term (â€œSDR Reportâ€) a form of which is attached hereto as Exhibit E. 15â€Œâ€‹â€‹3.5License for Process Patent.Licensee hereby grants to Penn a non-exclusive, world-wide, fully-paid, royalty-free, perpetual and irrevocable (subject to the last sentence herein) right and license with the right to sublicense in connection with a license of Pennâ€™s manufacturing processes (through multiple tiers), under (a) [*], (b) any continuations, provisionals, continued prosecution applications, substitutions, extensions and term restorations, registrations, confirmations, reexaminations, renewals or reissues thereof, including divisions, but excluding continuations-in-part except to the extent of claims entirely supported in the specification and entitled to the priority date of the parent application, and (c) any corresponding foreign Patent Rights to the foregoing (collectively, (a) through (c), the â€œProcess Patentâ€) to use and practice the same in order to make, have made, use, sell, offer for sale and import products ([*]) for any indications ([*]) in the Field of Use during the Term. The license granted under this Section 3.5 shall survive any expiration or termination of this agreement. Notwithstanding the foregoing, Licensee shall have the right to terminate such license upon written notice to Penn, with immediate effect, if Penn (A) [*] or (B) [*]. Â 3.6No Implied License.Each Party acknowledges that the rights and licenses granted in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights with respect to any Know-How, patent or other intellectual property right rights that are not specifically granted herein are reserved to the owner thereof.Article 4â€‹FINANCIAL PROVISIONS4.1Payments.4.1.1License Maintenance Fee. Beginning [*], and [*] thereafter until expiration of the Royalty Period, Licensee shall pay Penn a non-refundable, non-creditable annual maintenance fee of [*] (â€œLicense Maintenance Feeâ€); provided, however, that commencing after the First Commercial Sale of a Licensed Product, and payment of a Royalty due under 4.3.1, such License Maintenance Fee for each Calendar Year will be creditable towards Royalties due to Penn for such Calendar Year. 4.1.2Acknowledgment. The Parties acknowledge and agree that Licensee has fulfilled its obligations under Sections 4.1.1 (Issue Fee) and 4.1.2 (Equity Issuance) of the Original Agreement.4.1.3Discovery Funding. Â Within [*] following the Second Restatement Date, Licensee shall make a payment to Penn in the amount of [*] as payment for all amounts due and outstanding from Licensee to Penn with respect to Pennâ€™s conduct of the Discovery Program under the First ARCA.4.2Milestone Payments. 4.2.1Development Milestones.(a)As additional consideration for the License, Licensee will pay Penn the following milestone payments (each, a â€œDevelopment Milestone Paymentâ€) upon the 16â€Œâ€‹â€‹achievement of the corresponding milestone for each Licensed Product for the first Indication (each, a â€œDevelopment Milestoneâ€), whether achieved by Licensee or an Affiliate or Sublicensee. Licensee shall promptly notify Penn in writing of the achievement of any such Development Milestone and Licensee shall pay Penn in full the corresponding Development Milestone Payment within [*] of such achievement. For clarity, each Development Milestone Payment is non- refundable, is not an advance against Royalties due to Penn or any other amounts due to Penn.Development Milestone for Licensed Products for [*] Milestone Payment(in U.S. dollars) for each Licensed Product for the first Indication (except as noted in the column to the right)[*][*][*][*][*][*][*][*]â€‹Development Milestone for Licensed Products for [*]Milestone Payment(in U.S. dollars)â€‹[*][*][*]. â€‹(b)Notwithstanding anything to the contrary, to the extent a product is a Licensed Product solely by virtue of incorporating DRG Technology, and no other Penn Patent Right or Licensed Know-How, the milestone amounts set forth in the table above in Section 4.2.1(a) solely for such Licensed Product shall be replaced with the amounts set forth in the table below:Development MilestoneMilestone Payment(in U.S. dollars)â€‹[*][*][*][*][*][*]â€‹(c)Each time a Development Milestone is achieved for a Licensed Product for an Indication, then any other Development Milestone Payments with respect to earlier Development Milestones that have not yet been paid will be due and payable together with the Development Milestone Payment for the Development Milestone that is actually achieved. 17â€Œâ€‹â€‹(d)Notwithstanding the foregoing, in the event that the Licensed Product is applicable to any indication(s) outside of the named Indication in the applicable Completed Research Program (and Penn has the right to grant a License to such additional indication in accordance with Section 3.1), the foregoing milestones shall be due and payable by Licensee to Penn on such additional indication(s) as follows: (i) for a second indication of a Licensed Product, Licensee shall pay Penn [*] of the foregoing Development Milestones for the Licensed Product for the second indication, and (ii) for a third indication of the Licensed Product, Licensee shall pay Penn [*] of the foregoing Development Milestones for the Licensed Product for such third indication. No Development Milestones will apply to the fourth (or any later) indication of a given Licensed Product.(e)For clarity, Development Milestone Payments are due and payable on Licensed Product and on products that, upon Regulatory Approval, would become Licensed Product.4.2.2Commercial Milestone Payments.(a)As additional consideration for the License, Licensee will pay Penn the following commercial milestone payments (each, a â€œCommercial Milestone Paymentâ€) upon the achievement by Licensee or an Affiliate or Sublicensee of the corresponding milestone (each, a â€œCommercial Milestoneâ€), that is, when its worldwide Net Sales of a Licensed Product in a Calendar Year first reach the respective thresholds indicated below. Licensee shall promptly notify Penn in writing of the achievement of any such Commercial Milestone and Licensee shall pay Penn in full the corresponding Commercial Milestone Payment within [*] of such achievement. For clarity, [*].Commercial Milestone Event (payable once per Licensed Product [*]) One-Time Milestone Payment(U.S. dollars)[*][*][*][*][*][*][*][*]â€‹Commercial Milestone Event (payable once per Licensed Product [*])One-Time Milestone Payment(U.S. dollars)[*][*][*][*][*][*][*][*][*]â€‹Commercial Milestone Event (payable once per Licensed Product [*])One-Time Milestone Payment(U.S. dollars)[*][*][*][*][*][*][*][*] 18â€Œâ€‹â€‹[*][*]â€‹Commercial Milestone Event (payable once per Licensed Product [*])One-Time Milestone Payment(U.S. dollars)[*][*][*][*][*][*][*][*]â€‹(b)For clarity, the foregoing Commercial Milestone Payments shall be due once per Licensed Product.(c)[*]. 4.3Royalties.4.3.1Royalty. (a)As further consideration for the License, on a Licensed Product-by-Licensed Product and country-by-country basis during the Royalty Period, Licensee shall pay to Penn a non-refundable, non-creditable royalty on all Net Sales of each Licensed Product (â€œRoyaltyâ€) as set forth below:Annual Worldwide Net Sales(of the applicable Licensed Product)Royalty RateLess than [*][*]Greater than or equal to [*] and less than or equal to [*][*]Greater than [*][*]â€‹For clarity, the foregoing Royalty rates are tiered such that each rate applies only to the portion of annual Net Sales that is within the corresponding tier. That is, within any given Calendar Year, the first [*] of Net Sales of a given Licensed Product will accrue Royalties at [*], the next [*] of Net Sales of such Licensed Product will accrue Royalties at [*], and any Net Sales of such Licensed Product in excess of [*] will accrue Royalties at [*].(b)Notwithstanding anything to the contrary, to the extent a product is a Licensed Product solely by virtue of incorporating DRG Technology, and no other Penn Patent Right or Licensed Know-How, then the royalty rates set forth in the table above in Section 4.3.1(a) solely for such Licensed Product shall [*] for such Licensed Product.4.3.2Royalty Term. Licenseeâ€™s obligation to pay Penn the Royalty will continue on a country- by-country and Licensed Product-by-Licensed Product basis from the date of First Commercial Sale of such Licensed Product in a country until the latest of (a) the expiration of the last Valid Claim within the Penn Patent Rights and DRG Patent Rights covering such Licensed Product in the country in which such Licensed Product is made, used or sold, (b) the expiration of the data exclusivity term conferred by the applicable Regulatory Authority in such country with respect to such Licensed Product (e.g., such as in the case of an orphan drug), and (c) the tenth (10th) anniversary of the First Commercial Sale of 19â€Œâ€‹â€‹such Licensed Product in such country, subject to the terms of Section 6.5 (such royalty period, the â€œRoyalty Periodâ€).4.3.3Step-Down. On a country-by-country and Licensed Product-by-Licensed Product

basis, during any portion of the Royalty Period in which the applicable Licensed Product is not covered by at least one Valid Claim in the applicable country and is not subject to data exclusivity conferred by the applicable Regulatory Authority: (a) the Royalty rate under Section 4.3.1 shall be reduced to [*] of the Royalty rate otherwise payable pursuant to Section 4.3.1; and (b) no Royalty at all will apply to such Licensed Product [*].4.3.4Royalty Reductions.(a)Notwithstanding anything in this Section 4.3, in the event that Penn or Licensee receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. If any Third Party obtains a Compulsory License in any country, then: (i) Penn or Licensee (whoever has first notice) shall promptly notify the other Party; and (ii) beginning as of the date the Third Party obtained such Compulsory License in such country, the Royalty rate payable under this Section 4.3 to Penn for Net Sales in such country will be adjusted to [*].(b)Third Party Licenses.(i)If after the Second Restatement Date Licensee determines upon the advice of outside intellectual property counsel that a license to Patent Rights from a Third Party is reasonably necessary to develop, commercialize, or manufacture a Licensed Product, Licensee may obtain such a Third Party license to such Patent Rights.(ii)Licensee may deduct from any Royalty payments due to Penn under Section 4.3.1 of this Agreement an amount equal to [*].(iii)In the event that one or more Generic Product(s) with respect to a particular Licensed Product enter(s) the market in a particular country, and such Generic Product(s) in the aggregate have a market share of [*] or more in that country, Licensee may reduce the Royalty payments for Sales of such Licensed Product in such country by [*]; provided that if Licensee reduced the Royalty payments under this Section 4.3.4(b)(iii), Licensee shall resume making Royalty payments without reduction under this Section 4.3.4(b)(iii) as of the earlier of (A) no Generic Product being sold for at least [*] in such country and (B) a court of competent jurisdiction determines that a Valid Claim of a Penn Patent Right is valid and infringed by such Generic Product in such country.(iv)Notwithstanding the foregoing, in no event will the deductions under this Section 4.3.4(b) reduce the Royalty payable in respect of Net Sales of such Licensed Product in such country by more than [*] Â of the Royalty as set forth in SectionÂ 4.3.1 above.4.3.5Calculations. Licensee must pay Royalties owed to Penn on a Calendar Quarter basis on or before the following dates: 20â€Œâ€‹â€‹(a)[*] for any Sales that took place in the Calendar Quarter ending December 31, of the prior year;(b)[*] for any Sales that took place in the Calendar Quarter ending March 31 of such Calendar Year;(c)[*] for any Sales that took place in the Calendar Quarter ending June 30 of such Calendar Year; and(d)[*] for any Sales that took place in the Calendar Quarter ending September 30 of such Calendar Year.4.4Penn Sublicense Income.4.4.1For any given Licensed Product, Licensee will pay to Penn the following percentage of Sublicense Income (â€œPenn Sublicense Incomeâ€) received by Licensee from a Sublicensee (with no rights of apportionment):Stage in Licensed Product development at which sublicense is granted by Licensee% of Sublicense IncomePayable to Penn[*][*][*][*][*][*]â€‹â€‹4.4.2Notwithstanding Section 4.4.1, the Parties agree that [*]. For clarity, [*]. 4.4.3Licensee will make such payment to Penn on or before the following dates:(a)[*] for any Sublicense Income received by Licensee in the Calendar Quarter ending December 31, of the prior year;(b)[*] for any Sublicense Income received by Licensee in the Calendar Quarter ending March 31 of such Calendar Year;(c)[*] for any Sublicense Income received by Licensee in the Calendar Quarter ending June 30 of such Calendar Year; and(d)[*] for any Sublicense Income received by Licensee in the Calendar Quarter ending September 30 of such Calendar Year.4.5Mode of Payment and Currency.All payments to Penn hereunder shall be made by deposit of USD in the requisite amount to the â€œThe Trustees of the University of Pennsylvaniaâ€ and will be made by delivery to any one of the following:For funding of the performance of the Research Programs by Penn:By ACH/Wire:[*] 21â€Œâ€‹â€‹SWIFT CODE:[*] (international wires only) Account Number:[*]Payment should include the necessary amount to cover any bank charges incurred.For all other payments to Penn under this Agreement:By ACH/Wire:â€‹By Check (lockbox):[*] (domestic wires)â€‹The Trustees of the University of PennsylvaniaSWIFT CODE:[*]â€‹c/o Penn Center for Innovation(international wires only) Account Number:[*]â€‹PO Box 785546Philadelphia, PA 19178-5546â€‹â€‹Payment should include the necessary amount to cover any bank charges incurred.â€‹â€‹Payments under this Agreement shall be made in USD. All Royalties payable shall be calculated first in the currency of the jurisdiction in which payment was made, and if not in the United States, then converted into USD. The exchange rate for such conversion shall be the average of the rate quoted in The Wall Street Journal for the last business day of each month in the Calendar Quarter for such Royalty payment made.4.6Royalty and Penn Sublicense Income Reports.Within [*] after the end of each Calendar Quarter, Licensee shall deliver to Penn a report (â€œFinancial Reportâ€) setting out all details necessary to calculate the Royalty and Penn Sublicense Income due under this Article 4 for such Calendar Quarter, including:4.6.1[*];4.6.2Gross sales and Net Sales of each Licensed Product made by Licensee, its Affiliates and Sublicensees;4.6.3Royalties;4.6.4Sublicense Income and the calculation of Penn Sublicense Income;4.6.5The method and currency exchange rates (if any) used to calculate the Royalties and Penn Sublicense Income;4.6.6A specification of all deductions and their dollar value that were taken to calculate Net Sales; 22â€Œâ€‹â€‹4.6.7A list of all countries in which Licensed Product is being manufactured (on a product-by-product basis); and4.6.8Date of First Commercial Sale in the United States (this need only be reported in the first Financial Report following such First Commercial Sale in the United States).Each Financial Report shall be in the form of the sample report attached hereto as Exhibit F.4.7Late Payments.In addition to any other remedies available to Penn, including the right to terminate this Agreement as provided in Section 10.3, any failure by Licensee to make a payment within [*] after the date when due shall obligate Licensee to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Penn at a rate per annum equal to [*] per month, or the highest rate allowed by Law, whichever is lower.4.8Default Payment.In the event of default in payment of any payment owing to Penn under the terms of this Agreement, and if it becomes necessary for Penn to undertake legal action to collect said payment, Licensee shall pay reasonable, documented legal fees and costs incurred in connection therewith.4.9Accounting.Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.4.10Books and Records.Licensee will keep accurate books and records of all Licensed Products developed, manufactured, used or sold and all Sublicenses, collaboration agreements and joint venture agreements entered into by Licensee that involved Penn Patent Rights. Licensee will preserve these books and records for at least [*] from the date of the Financial Report to which they pertain. Upon reasonable notice, key personnel, books and records will be made reasonably available and will be open to examination by representatives or agents of Penn during regular office hours to determine their accuracy and assess Licenseeâ€™s compliance with the terms of this Agreement, provided that Licensee shall not have an obligation to provide access more than once in any given [*] period.4.11Audits.In addition to the right of Penn to examine the books and records and interview key personnel as provided in Section 4.10 above, Penn, at its own cost, through an independent auditor reasonably acceptable to Licensee (and who has executed an appropriate confidentiality agreement reasonably acceptable to Licensee that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Penn), may inspect and audit the relevant records of Licensee pertaining to the calculation of any Development Milestone Payments, Commercial Milestone Payments, Royalties and Penn Sublicense Income due to Penn under this Agreement. Licensee shall provide such auditors with access to the records during reasonable business hours. Such access need not be given to any such set of records more often than once each year or more than [*] after the date of any report to be audited. Penn shall provide Licensee with written notice of its election to inspect and audit the records related to the Development Milestone Payments, 23â€Œâ€‹â€‹Commercial Milestone Payments and Royalties due hereunder not less than [*] prior to the proposed date of review of Licenseeâ€™s records by Pennâ€™s auditors. Should the auditor find any underpayment of Development Milestone Payments, Commercial Milestone Payments, Royalties or Penn Sublicense Income by Licensee, Licensee shall (a) promptly pay Penn the amount of such underpayment; (b) shall reimburse Penn for the cost of the audit, if such underpayment equals or exceeds the higher of (i) [*] or (ii) [*] of combined Development Milestone Payments, Commercial Milestone Payments, Royalties and Penn Sublicense Income paid during the time period audited; and (c) provide such auditors with an audit right exercisable within [*] after Penn receives the audit report. If the auditor finds overpayment by Licensee, then Licensee shall have the right to deduct the overpayment from any future Development Milestone Payments, Commercial Milestone Payments, Royalties or Sublicense Income due to Penn by Licensee or, if no such future Development Milestone Payments, Commercial Milestone Payments, Royalties or Sublicense Income are payable, then Penn shall refund the overpayment to Licensee within [*] after Penn receives the audit report. [*].4.12Taxes.All payments made by Licensee to Penn under the Agreement shall be made free and clear of and without any deduction for or on account of any Taxes on or with respect to such payments.Article 5â€‹CLINICAL DEVELOPMENT, REGULATORY AFFAIRS; COMMERCIALIZATION5.1Development Plan.Licensee shall provide Penn with a development plan no later than [*] during the Term. The development plan shall include a timeline for detailed activities to be conducted by Licensee, its Affiliates and Sublicensees, and Licensee shall provide Penn with [*] progress reports regarding achievements and activities under such development plan. For clarity, [*].5.2Clinical.Licensee shall have the first right to sponsor all clinical activities and lead regulatory interactions for the Licensed Products for each Indication under this Agreement. Without limiting the foregoing, Licensee will have the first option, but not an obligation, to conduct a FIH Clinical Study for each Licensed Product developed under the Completed Research Programs. Licensee will consider in good faith using Penn as a study site for one or more studies where Penn can reasonably demonstrate that Pennâ€™s capabilities and costs are reasonably comparable to other potential study sites. If Penn (in its sole discretion) is willing and able to conduct a Clinical Study for a Licensed Product developed under the Completed Research Programs, the Parties will negotiate a separate clinical trial agreement and a separate clinical trial budget prior to initiation of such Clinical Study. 5.3Commercialization.Licensee will have sole responsibility for and sole decision-making over all commercialization activities of the Licensed Products for the Indications in the Field of Use, and will be solely responsible for the associated costs of such commercialization activities.5.4Manufacturing.Licensee will have responsibility for and decision-making authority over all manufacturing activities and associated costs for the clinical development (including cGMP manufacturing for 24â€Œâ€‹â€‹clinical trials) and commercialization of the Licensed Products in the Field of Use for the Indications post-DTP for such Licensed Product. 5.5Regulatory.5.5.1Licensee will have responsibility for and decision-making over regulatory activities for the Licensed Products for the Indications in the Field of Use. Licensee will have the right to conduct all communications with Regulatory Authorities, including all meetings, conferences and discussions (including advisory committee meetings), with regard to Licensed Products for the Indications in the Field of Use. Licensee will lead and have control over preparing and submitting all regulatory filings related to the Licensed Products for the Indications in the Field of Use, including all applications for Regulatory Approval, provided, however, that Licensee shall provide Penn with copies of all such applications prior to submission to the extent such submission includes Research Results or any Confidential Information of Penn. Licensee will own any and all applications for Regulatory Approvals (including INDs), Regulatory Approvals, and other regulatory filings related to the Licensed Product for the Indication in the Field of Use, which will be held in the name of Licensee or its designees.5.5.2Until [*], Penn will use commercially reasonable efforts to cooperate with any reasonable request from Licensee with respect to obtaining any Regulatory Approval for a Licensed Product for the Indication in the Field of Use including, [*]: (a) [*]; (b) responding to questions raised by Licensee; and (c) [*]. Â Notwithstanding the foregoing, [*], upon any reasonable request from Licensee with respect to obtaining any Regulatory Approval for a Licensed Product for the Indication in the Field of Use, Penn will, [*]. 5.6General Diligence.Licensee will use Commercially Reasonable Efforts to actively develop, obtain Regulatory Approval and commercialize at least one Licensed Product in each Indication within the Field of Use.5.7Acknowledgment.The Parties acknowledge and agree that Licensee has fulfilled its obligations under Section 5.7 (Financial Diligence) of the Original Agreement.5.8Diligence Events.5.8.1Licensee, itself or through any of its Affiliates or Sublicensees, shall achieve each of the following Diligence Events by the corresponding Achievement Date for each Licensed Product:Diligence EventAchievement Date [*][*][*][*][*][*]â€‹â€‹Penn acknowledges that the timeline for each Achievement Date is based on the assumption that development and commercialization of a Licensed Product does not encounter material regulatory or other delays for reasons outside of Licenseeâ€™s reasonable 25â€Œâ€‹â€‹control. Where such circumstances exist, Penn agrees to negotiate in good faith with Licensee, upon Licenseeâ€™s written request and provided such request is made at least [*] prior to the Achievement Date for a Diligence Event, an extension of the Achievement Date for a Diligence Event for such Licensed Product as reasonably requested by Licensee. If the Parties have not agreed on a requested extension within [*] of such request, [*].To the extent Licensee has achieved any Diligence Event by the corresponding Achievement Date in relation to a given Licensed Product for an Indication, Licensee will be deemed to have also met its diligence obligations under Section 5.6 with respect to such Licensed Product and its associated Indication(s) through the corresponding Achievement Date.5.8.2During the Term, for all Licensed Products for [*], upon Pennâ€™s reasonable request, Licensee (or, with respect to any Licensed Product that is sublicensed by Licensee to a Specified Sublicensee, such Specified Sublicensee) shall provide Penn an update to the development plan delivered [*] under Section 5.1 for any such Licensed Product describing the status of the clinical development thereof. If, following such review, Penn in good faith reasonably believes that Licensee (or the Specified Sublicensee, as applicable) has [*] period, and such [*] is not: (a) [*]; (b) [*]; (c) [*]; (d) [*]; or (e) [*], then Penn shall submit such matter for [*]. [*] shall be conducted in accordance with [*], the determination by [*] shall be completed within [*] after the initial submission to [*], and the [*] shall be shared equally by the Parties. If (i) [*] finds that Licensee (or the Specified Sublicensee, as applicable) has [*] as set forth above, and (ii) Licensee (or the Specified Sublicensee, as applicable) does not [*] of the [*], Penn will have the right to [*]. 5.9Progress Reports.5.9.1Licensee on an [*], but in no event later than [*], shall submit to Penn a progress report (each, a â€œProgress Reportâ€) covering Licenseeâ€™s (and any Affiliatesâ€™ and Sublicenseesâ€™) activities related to the development of all Licensed Products in each Indication and the obtaining of Regulatory Approvals necessary for commercialization of Licensed Products.5.9.2Each Progress Report must include all of the following for each annual period: (a)Summary of material development activities;(b)Summary of material commercialization activities;(c)Identification of filings for Regulatory Approval and other material correspondence with Regulatory Authorities;(d)An updated SDR Report listing of any and all Sublicenses granted by Licensee; and(e)The names and addresses of all Sublicensees, and a current and valid phone number and e-mail address for a principal point of contact at each such Sublicensee who is responsible for administering the Sublicensee. 26â€Œâ€‹â€‹Article 6â€‹INTELLECTUAL PROPERTY6.1Patent Filing Prosecution and Maintenance.6.1.1Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights will be held in the name of Penn and obtained with counsel selected by Penn and reasonably acceptable to Licensee (â€œPatent Counselâ€). Penn shall control all actions and decisions with respect to the filing, prosecution and maintenance of Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights. Penn will provide Licensee with advance copies of filings of the Penn Patent Rights, Discovery Patent Rights and will consider in good faith reasonable comments and suggestions by Licensee, and [*] (collectively, the â€œProduct Specific Patent Rightsâ€), Penn will incorporate any reasonable comments or suggestions by Licensee with respect to same. Penn will instruct Patent Counsel to copy Licensee on all correspondence related to Penn Patent Rights A and Penn Patent Rights B (including copies of each patent application, office action, response to office action, request for terminal disclaimer, and request for reissue or reexamination of any patent or patent application) and to interact with Licensee with respect to the preparation, filing, prosecution and maintenance of Penn Patent Rights A and Penn Patent Rights B. Penn has the right to take action to preserve rights and minimize cost [*], and will use reasonable efforts to not allow any Penn Patent Rights and DRG Patent Rights for which Licensee is licensed and is underwriting the costs to lapse or become abandoned without Licenseeâ€™s written authorization under this Agreement, [*], provided that, Penn shall have no requirement to file, prosecute, or maintain Penn Patent Rights, Discovery Patent Rights or DRG Patent Rights if Licensee is not current with the Patent Cost obligations as set forth in this Agreement. For the purposes of this Agreement, â€œmaintenanceâ€ of the Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights includes [*], provided Pennâ€™s participation in such proceedings is undertaken in good-faith consultation with Licensee. For further clarity, [*] will be handled pursuant to the provisions of Section 6.3.6.1.2Licensee has the right to request a country filing via a written request to Penn [*] prior to the deadline set by the patent office in the territory in which filing is to take place (â€œProsecution Requestâ€), and Penn shall in connection with Section 6.1.1 provide written notice to Licensee of filing, prosecution and maintenance with respect to the Penn Patent Rights. If Penn files a patent application, prosecutes or maintains any Penn Patent Rights in any country, Licensee shall, in connection with Section 6.2, be responsible for its pro rata share of such filing, prosecution or maintenance of the Penn Patent Right, unless Licensee provides written notice to Penn of its election to abandon such Penn Patent Right. Upon written notice to Penn of Licenseeâ€™s election to abandon any such Penn Patent Right in any such country, such Patent Rights for such country will not be part of Penn Patent Rights and therefore not subject to this Agreement, including the License, and Licensee will have no further rights or license to them in such country.6.1.3In the event that DRG Technology [*], then Penn may file and prosecute a Patent Right that covers [*]; provided, however, that if Penn files a [*].6.2Patent Costs.6.2.1Subject to Section 6.2.3, within [*] of the Second Restatement Date, Licensee will reimburse Penn for all out-of-pocket costs for the filing, prosecution and maintenance of Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights, including all accrued 27â€Œâ€‹â€‹attorney fees, expenses, official and filing fees (â€œPatent Costsâ€) for Discovery Patent Rights and DRG Patent Rights, incurred prior to the Second Restatement Date that have not otherwise been reimbursed by other licensees on a pro rata basis (â€œHistoric Patent Costsâ€). The amount of Historic Patent Costs invoiced to, but not yet paid by, Passage as of [*] is [*]. For clarity, [*].6.2.2Licensee will bear all Patent Costs incurred during the Term (â€œOngoing Patent Costsâ€), on a pro rata basis (as described below) where applicable. For Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights licensed or optioned to more than one licensee, Licensee shall be responsible for payment to Penn of a pro rata share of such Ongoing Patent Costs based on the number of licensees for such Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights (which Penn

will disclose to Licensee upon Licenseeâ€™s exercise of an applicable option, and whenever such number changes, and at any other time upon Licenseeâ€™s reasonable written request). 6.2.3At any time, at Pennâ€™s request, Licensee shall pay its relevant share in advance the Patent Counselâ€™s estimated costs for undertaking material patent actions before Penn authorizes the Patent Counsel to proceed (â€œAdvance Paymentâ€). Notwithstanding whether Licensee makes an Advance Payment for any patent action, Licensee shall bear all Patent Costs incurred during the Term (on a pro rata basis as applicable) and shall pay such amounts within [*] of receipt of invoice for such patent actions. For clarity, [*].6.2.4In the event that Licensee provides Penn at least [*] advance written notice to elect not to pay Historic Patent Costs or Ongoing Patent Costs for any Penn Patent Right, Discovery Patent Right or DRG Patent Right in any country, upon the effective date of such notice, such patent or patent application shall no longer be part of the License granted to Licensee in Section 3.1 or the Penn Patent Rights for purposes of this Agreement (including the provisions of this Section 6.2) and Licensee shall not be entitled to receive a license to such Penn Patent Right, Discovery Patent Right or DRG Patent Right in such country in the future. In addition, for such rejected Penn Patent Right or Discovery Patent Right, the Licensing Exclusivity Period or ability to add such rejected Penn Patent Right or Discovery Patent Right to the license grant as set forth in Section 2.4 shall terminate immediately. 6.2.5Licensee shall also have the right, on a DRG Patent Right-by-DRG Patent Right and country-by-country basis, to (a) elect not to fund at the time of disclosure, or (b) elect not to continue to fund, in each case (a) and (b), its pro rata share (as determined pursuant to Section 6.2.2 above) of the Patent Costs with respect to any DRG Patent Right(s) in a particular country, which election may be made by Licensee upon [*] prior written notice to Penn (â€œDRG Election Noticeâ€). If Licensee delivers a DRG Election Notice to Penn, following the expiration of such [*] period, Licensee shall have no further obligation to pay Ongoing Patent Costs with respect to any DRG Patent Right identified in such DRG Election Notice in any country identified in such DRG Election Notice and any such Patent Right in any such country shall thereafter be excluded from the DRG Patent Rights.6.3Infringement.6.3.1If either Party believes that an infringement by a Third Party with respect to any Penn Patent Right or DRG Patent Right is occurring or may potentially occur, the knowledgeable Party will provide the other Party with (a) written notice of such infringement or potential infringement and (b) evidence of such infringement or potential infringement (the â€œInfringement Noticeâ€). Licensee shall [*] without first obtaining the written consent of 28â€Œâ€‹â€‹Penn, which consent will not be unreasonably withheld. If Licensee [*], then Licenseeâ€™s right to initiate a suit under Section 6.3.2 below will terminate immediately without the obligation of Penn to provide notice to Licensee. Both Penn and Licensee will use their diligent efforts to cooperate with each other to terminate such infringement without litigation.6.3.2If infringing activity [*] has not been abated within [*] following the date the Infringement Notice for such activity was provided, then (except as otherwise provided in Section 6.3.4) during [*], the â€œExclusive Penn Patent Rightsâ€), and the infringement is [*], Licensee may institute suit for patent infringement of an [*] against the infringer after providing Penn (a) [*] and (b) [*]. For clarity, [*]. Penn may voluntarily join such suit at Licenseeâ€™s reasonable expense, [*]. If in a claim initiated by Licensee, Penn is involuntarily joined other than by Licensee, then Licensee [*]. Licensee shall be free to enter into a settlement, consent judgment or other voluntary disposition, provided that any settlement, consent judgment or other voluntary disposition that (i) [*] or (ii) [*]. Licenseeâ€™s request for such approval shall include complete copies of final settlement documents, a detailed summary of such settlement, and any other information material to such settlement. Penn shall provide Licensee notice of its approval or denial within [*] of any request for such approval by Licensee, provided that (A) [*] and (B) [*].6.3.3If, within [*] following the date the Infringement Notice was provided, infringing activity of [*] has not been abated and if Licensee has not brought suit against the infringer, then Penn [*]. If Penn [*], then Licensee may [*].6.3.4Notwithstanding Sections 6.3.2 and 6.3.3, (a) in the event that any Penn Patent Rights are infringed by a Third Party [*] or (b) if any of the infringed Penn Patent Rights are [*], the Parties shall discuss, and will mutually agree, in writing, as to how to handle such infringement by such Third Party. Furthermore, with respect to any Penn Patent Rights A that are not Product Specific Patent Rights, and/or any Penn Patent Rights B, Licensee may [*]. For clarity, [*] right to enforce (i) Penn Patent Rights B, unless otherwise agreed in writing by the Parties ([*]), and (ii) Manufacturing Patent Rights.6.3.5Any recovery or settlement received in connection with any suit will first be [*] and [*]. Any remaining recoveries shall be allocated as follows:For any portion of the recovery or settlement, other than for amounts attributable and paid as enhanced damages for [*]:(a)for any suit that is initiated by Licensee and in which Penn was not a party in the litigation, Penn shall receive [*] of the recovery and the Licensee shall receive the remainder; and(b)for any suit that is initiated by the Licensee or Penn and that the other Party joins voluntarily ([*]) or involuntarily, the non-initiating Party shall receive [*] of such recovery, while the initiating Party shall receive the remainder.For any portion of the recovery or settlement paid as enhanced damages for [*]:(c)for any suit that is initiated by Licensee or Penn and the other Party joins voluntarily ([*]) or involuntarily, Penn shall receive [*] and Licensee shall receive the remainder; and 29â€Œâ€‹â€‹(d)for any suit that is initiated by Licensee and in which Penn was not a party in the litigation, Penn shall receive [*] and Licensee shall receive the remainder.For any portion of the recovery or settlement received in connection with any suit that is initiated by Penn and in which Licensee was not a party in the litigation, any recovery in excess of litigation costs will belong to Penn.6.3.6Each Party will reasonably cooperate and assist with the other in litigation proceedings instituted hereunder but at the expense of the Party who initiated the suit (unless such suit is being jointly prosecuted by the Parties). For clarity, [*]. If Penn is subjected to Third Party discovery related to the Penn Patent Rights or Licensed Products licensed to Licensee hereunder, Licensee will pay Pennâ€™s documented out of pocket expenses with respect to same.6.4Patent Marking.Licensee shall place in a conspicuous location on any Licensed Product (or its packaging where appropriate and practicable) made or sold under this Agreement a patent notice in accordance with the Laws concerning the marking of patented articles where such Licensed Product is made or sold, as applicable.6.5Patent Term Extensions.[*].Subject to the terms set forth in this Section 6.5, in each instance the non-filing Party shall abide by such election and the terms set forth herein and cooperate as reasonably requested by the other Party in connection with the foregoing (including by providing appropriate information and executing appropriate documentation). The filing Party shall provide the non-filing Party a copy of such filing in advance and will consider in good faith reasonable comments and suggestions by the non-filing Party. Licensee shall ensure that all Sublicensees and Affiliates are bound by the terms and conditions set forth in this Section 6.5.Article 7â€‹CONFIDENTIALITY& PUBLICATION7.1Confidential Information.Licensee shall not disclose Confidential Information (as defined below) to Penn unless it is anticipated to be necessary or useful to the performance of any of the Research Programs or is reasonably responsive to Licenseeâ€™s reporting obligations under this Agreement or any other request of Penn. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] thereafter, the receiving Party (the â€œReceiving Partyâ€) and its Affiliates will keep confidential and will not publish or otherwise disclose or use for any purpose, other than as provided for in this Agreement, any confidential or proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise), including trade secrets, Know-How, inventions or discoveries, proprietary information, formulae, processes, techniques and information relating to the past, present and future marketing, financial, and research and development activities of any product or potential product or useful technology of the Disclosing Party or its Affiliates and the pricing thereof (collectively, â€œConfidential Informationâ€), which is disclosed to it by the other 30â€Œâ€‹â€‹Party (the â€œDisclosing Partyâ€) or its Affiliates or otherwise received or accessed by a Receiving Party in the course of performing its obligations or exercising its rights under this Agreement.7.2Exceptions to Confidentiality.â€œConfidential Informationâ€ does not include information that (a) was in the lawful knowledge and possession of the Receiving Party or its Affiliates prior to the time it was disclosed to, or learned by, the Receiving Party or its Affiliates, or was otherwise developed independently by the Receiving Party or its Affiliates, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the Receiving Party or its Affiliates; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party or its Affiliates, as evidenced by written records of the Receiving Party or its Affiliates; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party or its Affiliates in breach of this Agreement; or (d) was disclosed to the Receiving Party or its Affiliates, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party or its Affiliates not to disclose such information to others. In the event a Receiving Party is required to make a disclosure under Law or regulation, the order of a court of competent jurisdiction, or the rules of the U.S. Securities and Exchange Commission (including by reason of any securities offering by Licensee), any stock exchange or listing entity, such disclosure will not constitute a breach of this Article 7 provided such Receiving Party shall provide [*] to the Disclosing Party and take all reasonable steps to limit the extent of the disclosure and obtain confidential treatment for any remaining required disclosure.7.3Penn Intellectual Property.In order to preserve the patentability of Penn intellectual property and to preserve Pennâ€™s publication rights, Licensee shall [*].7.4Publications.Penn shall have the sole and exclusive first right to publish, publicly present or otherwise publicly disclose Research Results for any purpose, subject to the following provisions; provided, however, that if Licensee provides written request to Penn to publish, publicly present or otherwise publicly disclose the Research Results, and Penn does not publish, publicly present or otherwise publicly disclose such Research Results within [*], Licensee shall be entitled to publish, publicly present or otherwise publicly disclose such Research Results in accordance with the provisions of this Section 7.4. Penn shall furnish the Licensee with a copy of any proposed publication, presentation, or other public disclosure at least [*] in advance of the date of such presentation or public disclosure or the submission of said proposed publication in order for Licensee to review and comment on said proposed publication, presentation, or other public disclosure to (a) determine whether such contains any Licensee Confidential Information and (b) enable Licensee to identify any Penn intellectual property that it wishes Penn to file patent applications on or to seek other intellectual property protection for. If within the [*] review period (i) Licensee notifies Penn in writing that the Licensee [*] deletion of Licensee Confidential Information from the publication, presentation, or other disclosure, the Parties will cooperate to modify the same to ensure Licensee Confidential Information is not disclosed or (ii) if Licensee requests in writing that publication, presentation, or other disclosure be delayed to allow for patent filings or other intellectual property protection on certain items in the proposed publication, presentation, or other disclosure, Penn shall delay the same for up to [*] to allow for the filing of patent applications or other intellectual property protection. For clarity [*]; provided, however, [*]. 31â€Œâ€‹â€‹Article 8â€‹REPRESENTATIONS, WARRANTIES AND COVENANTS8.1Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Second Restatement Date: 8.1.1such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;8.1.2such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;8.1.3this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditorsâ€™ rights generally and by general equitable principles; and8.1.4such Party has all right, power and authority to enter into this Agreement, to perform its obligations under this Agreement. 8.2Representations and Warranties of Penn. Penn hereby represents and warrants to Licensee that, as of the Second Restatement Date: 8.2.1Penn Controls all Penn Patent Rights A;8.2.2[*];8.2.3subject to the Specified Obligations and except with respect to the Transferred Research Programs, Penn has neither granted nor agreed to grant, any license to the Exclusive Penn Patent Rights in the CNS Field in the Field of Use anywhere in the world;8.2.4[*]; 8.2.5all data included in the Licensed Know-How and/or which has been or will be used to support the filing, prosecution or maintenance of the Penn Patent Rights has been generated, and prior to the Second Restatement Date the Research Programs have been conducted, in a thorough and professional manner; 8.2.6[*]; and8.2.7[*]. 8.3Disclaimer of Representations and Warranties.8.3.1Other than the representations and warranties provided in Sections 8.1 and 8.2 above, PENN MAKES NO REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS OR IMPLIED, AND EXPLICITLY DISCLAIMS ANY REPRESENTATION AND WARRANTY, INCLUDING WITH RESPECT TO ANY ACCURACY, COMPLETENESS, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, COMMERCIAL UTILITY, NON-INFRINGEMENT 32â€Œâ€‹â€‹OR TITLE FOR THE INTELLECTUAL PROPERTY, PATENT RIGHTS, LICENSE AND ANY LICENSED PRODUCT.8.3.2Furthermore, nothing in this Agreement will be construed as:(a)A representation or warranty by Penn as to the validity or scope of any Penn Patent Right, Discovery Patent Right or DRG Patent Right;(b)A representation or warranty that anything made, used, sold or otherwise disposed of under the License is or will be free from infringement of patents, copyrights, trademarks or any other forms of intellectual property rights or tangible property rights of Third Parties;(c)Obligating Penn to bring or prosecute actions or suits against Third Parties for patent, copyright or trademark infringement; and(d)Conferring by implication, estoppel or otherwise any license or rights under any Patent Rights of Penn other than Penn Patent Rights and DRG Patent Rights as defined herein, regardless of whether such Patent Rights are dominant or subordinate to Penn Patent Rights or DRG Patent Rights.8.3.3Licensee acknowledges and agrees that it has conducted diligence relating to the Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights, and has been offered the opportunity to ask representatives of Penn questions about Penn Patent Rights, Discovery Patent Right and DRG Patent Rights. Penn represents that it has provided such available information as Licensee has requested relating to such Penn Patent Rights, Discovery Patent Rights and DRG Patent Rights and any additional available information that Penn knows to be material to the diligence conducted by Licensee.8.4Covenants of Licensee.8.4.1Licensee and its Affiliates will not, directly or indirectly (including where such is done by a Third Party on behalf of Licensee or its Affiliates, at the urging of Licensee or its Affiliates or with the assistance of the Licensee or its Affiliates) institute or make any Challenge; provided, however, that if any Penn Patent Right, Discovery Patent Rights or DRG Patent Right is asserted against Licensee or its Affiliate for activities authorized under this Agreement, then Licensee or its Affiliates (or the Sublicensee or sub-Sublicensee) is entitled to all and any defenses available to it including challenging the validity or enforceability of such Patent Right.8.4.2Licensee will comply with all Laws that apply to its activities or obligations under this Agreement. For example, Licensee will comply with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the applicable agency of the United States government and/or written assurances by Licensee that Licensee will not export data or commodities to certain foreign countries without prior approval of the agency.8.4.3Licensee will not grant a security interest in any Penn Patent Rights, Discovery Patent Rights or DRG Patent Right. 33â€Œâ€‹â€‹Article 9â€‹INDEMNIFICATION; INSURANCE AND LIMITATION OF LIABILITY9.1Indemnification by Licensee.9.1.1Licensee shall defend, indemnify and hold Penn and its respective trustees, officers, faculty, students, employees, contractors and agents (the â€œPenn Indemniteesâ€) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneysâ€™ fees), including, without limitation, bodily injury, risk of bodily injury, death and property damage arising out of Third Party claims or suits related to:(a)the negligence, recklessness or wrongful intentional acts or omissions of Licensee, its Affiliates or Sublicensees and its or their respective directors, officers, employees and agents, in connection with Licenseeâ€™s performance of its obligations or exercise of its rights under this Agreement or the First ARCA;(b)any breach of this Agreement or the First ARCA by Licensee;(c)the development, manufacturing or commercialization (including commercial manufacturing, packaging and labeling of Licensed Products, and all product liability losses) of a Licensed Product by or on behalf of Licensee or its Affiliates or Sublicensees; or(d)any enforcement action or suit brought by Licensee against a Third Party for infringement of Penn Patent Rights;provided that Licenseeâ€™s obligations pursuant to this Section 9.1 shall not apply to the extent such claims or suits result from the gross negligence or willful misconduct of any of Penn Indemnitees as determined by a court of law.9.1.2As a condition to a Penn Indemniteeâ€™s right to receive indemnification under this SectionÂ 9.1, Penn shall: (a) promptly notify Licensee as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) reasonably cooperate, and cause the individual Penn Indemnitees to reasonably cooperate, with Licensee in the defense, settlement or compromise of such claim or suit; and (c) permit the Licensee to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may Licensee compromise or settle any claim or suit in a manner which (i) admits fault or negligence on the part of Penn or any other Penn Indemnitee; (ii) commits Penn or any other Penn Indemnitee to take, or forbear to take, any action, without the prior written consent of Penn; or (iii) grant any rights under the Penn Patent Rights or DRG Patent Rights except for Sublicenses permitted under Section 3.4. Penn shall reasonably cooperate with Licensee and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses.9.1.3Notwithstanding Section 9.1.2 above, in the event that Penn believes in good faith that a bona fide conflict exists between Licensee and Penn or any other Penn Indemnitee with respect to a claim or suit subject to indemnification hereunder, then Penn or any other Penn Indemnitee shall have the right to defend against any such claim or suit itself, including by selecting its own counsel, with any reasonable attorneyâ€™s fees and litigation expenses being 34â€Œâ€‹â€‹paid for by Licensee. Licensee will pay such fees and expenses either directly or will reimburse Penn within [*] of Licenseeâ€™s receipt of invoices for such fees and expenses.9.2Insurance.9.2.1Beginning no later than commencement of the first Clinical Study for any Licensed Product, Licensee, at its sole cost and expense, must insure its activities in connection with the exercise of its rights under this Agreement and obtain, and keep in force and maintain Commercial Form General Liability Insurance (contractual liability included) with limits as follows:(a)Each occurrence[*];(b)General aggregate[*]Prior to the commencement of clinical trials, if applicable, involving Licensed Product:(c)Clinical trials liability insurance[*]Prior to the First Commercial Sale of a Licensed Product:(d)Products liability insurance[*]Penn may review

periodically the adequacy of the minimum amounts of insurance for each coverage required by this Section 9.2.1, and has the right to require Licensee to adjust the limits in Pennâ€™s reasonable discretion.9.2.2If the above insurance is written on a claims-made form, it shall continue for [*] following termination or expiration of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the Original Effective Date.9.2.3Licensee expressly understands, however, that the coverages and limits in Section 9.2.1 do not in any way limit Licenseeâ€™s liability or indemnification obligations. Licenseeâ€™s insurance will:(a)Be issued by an insurance carrier with an [*] or better;(b)Provide for [*] advance written notice to Penn of any modification;(c)State that Penn is endorsed as an additional insured with respect to the coverages in Section 9.2.1; and(d)Include a provision that the coverages will be primary and will not participate with nor will be excess over any valid and collective insurance or program of self insurance carried or maintained by Penn.9.2.4Licensee must furnish to Penn with (a) valid certificate of insurance evidencing compliance with all requirements of this Agreement and (b) additional insured endorsements for Licenseeâ€™s applicable policies naming â€œThe Trustees of the University of Pennsylvaniaâ€ as an additional insured. Licensee must furnish both documents within [*] each year and at any time there is a modification in such insurance. 35â€Œâ€‹â€‹9.3LIMITATION OF LIABILITY.EXCEPT FOR DAMAGES ARISING FROM A BREACH OF ARTICLE 7 OR DAMAGES ARISING FROM A PARTYâ€™S INDEMNIFICATION OBLIGATIONS UNDER THIS AGREEMENT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF.Article 10â€‹TERM AND TERMINATION10.1Term.The term of this Agreement (the â€œTermâ€) became effective on the Original Effective Date and, unless terminated sooner as provided below, shall continue in full force and effect will continue in effect on a country-by-country and Licensed Product-by-Licensed Product basis until the latest of (a) expiration of the last Valid Claim of the Penn Patent Rights or DRG Patent Right in such country for such Licensed Product and (b) expiration of the Royalty Period, whereupon the License to such country for such Licensed Product will become perpetual and fully paid-up. Â 10.2Termination of the Agreement for Convenience.Licensee may, at its convenience, terminate this Agreement or terminate any Licensed Product for an Indication in the Field of Use, upon providing at least ninety (90) days prior written notice to Penn of such intention to terminate, provided that upon termination Licensee ceases using the License for making, using, or selling the affected Licensed Product(s) in all Fields of Use.10.3Termination For Cause.10.3.1Subject to Section 10.3.4, in the event Licensee fails to achieve any Diligence Event by the corresponding Achievement Date (as the same may be extended under this Agreement in accordance with Section 5.8) and does not cure such breach within [*] written notice (or a longer period of up to [*] if the Parties mutually agree that such longer period is necessary and acceptable) to the reasonable satisfaction of Penn, Penn has the right and option to terminate this Agreement on an Indication-by-Indication basis for the Indication in which diligence has not been achieved, upon written notice, with immediate effect.10.3.2Subject to Section 10.3.4, in addition to all other remedies available to it, Penn may terminate this Agreement (a) upon [*] written notice if Licensee fails to comply with any Laws that apply to its activities or obligations under this Agreement, which failure(s) can be remedied, and Licensee fails to remedy such lack of compliance within such [*] period, (b) in its entirety, upon written notice, with immediate effect, if Licensee grants a security interest in any Penn Patent Right, Discovery Patent Right or DRG Patent Right, or (c) in its entirety, upon written notice, with immediate effect, if Licensee breaches Section 8.4.1. 10.3.3Subject to Section 10.3.4, if either Party materially breaches any of its material obligations under this Agreement, the non-breaching Party may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its 36â€Œâ€‹â€‹intention to terminate this Agreement. If such breach is not cured within [*] of such notice for non-payment ([*]), and [*] of such notice for all other material breaches, such termination shall become effective upon a notice of termination by the terminating Party thereafter; provided, however, [*]. In addition, [*].10.3.4Notwithstanding anything to the contrary, Penn shall not have the right to terminate this Agreement (in its entirety nor on an Indication-by-Indication basis) for an uncured breach by a Specified Sublicensee if (a) [*], and (b) [*]. Â 10.3.5Either Party may terminate this Agreement, upon written notice, with immediate effect if, at any time, the other Party is unable to pay its debts, including any debts related to exclusive sublicensees, when they come due, or files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition for the appointment of a receiver or trustee of such Party or of its assets, or if such Party proposes a written agreement of composition or extension of its debts, or if such Party is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition is not dismissed within [*] after the filing thereof, or if such Party is a party to any dissolution or liquidation, or if such Party makes an assignment for the benefit of its creditors of all or substantially all its assets.10.4Effects of Termination.10.4.1Notwithstanding the termination of this Agreement, the following provisions shall survive: Sections [*]. Furthermore, where this Agreement is terminated in relation to fewer than all of the Indications or Licensed Products (as provided above), it will remain in effect as to the non-terminated Indication(s) or non-terminated Licensed Product(s).10.4.2Termination of this Agreement shall not relieve the Parties of any obligation or liability that, at the time of termination, has already accrued hereunder, or which is attributable to a period prior to the effective date of such termination. Termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Partyâ€™s right to obtain performance of any obligation.10.4.3If this Agreement is terminated for any reason, all outstanding Sublicenses (including all Sublicense Documents for each Sublicense) not in default will be assigned by Licensee to Penn, and such assignment will be accepted by Penn provided that such Sublicensee is required to comply with all obligations, including financial obligations, set forth in this Agreement of the Licensee. Each assigned Sublicense will remain in full force and effect with Penn as the licensor or sublicensor instead of Licensee, but the duties and obligations of Penn under the assigned Sublicenses will not be greater than the duties of Penn under this Agreement, and the rights of Penn under the assigned Sublicenses will not be less than the rights of Penn under this Agreement, including all financial consideration and other rights of Penn. Penn may, at its reasonable discretion, amend such outstanding Sublicenses to contain the terms and conditions found in this Agreement. If Penn requests that Licensee assign to Penn all Regulatory Approvals for the Licensed Product upon termination of this Agreement by Licensee under Section 10.2 or by Penn under Section 10.3, then Licensee agrees to negotiate the terms of such an assignment in good faith (it being understood that the foregoing will not preclude Licensee from requiring Penn to pay commercially reasonable consideration for such assignment). [*]. 37â€Œâ€‹â€‹10.4.4Upon termination of this Agreement, the License immediately terminates and Licensee, its Affiliates and Sublicensees will promptly cease selling the Licensed Product(s) subject to such termination. Each Party will return (or destroy, as directed by the other Party) all data, files, records and other materials containing or comprising the other Partyâ€™s Confidential Information with respect to this Agreement, except to the extent such Confidential Information is necessary or useful to conduct activities in connection with surviving portions of this Agreement. Notwithstanding the foregoing, the Parties will be permitted to retain one copy of such data, files, records, and other materials for archival and legal compliance purposes.10.4.5Upon termination of this Agreement or any Licensed Product for an Indication in the Field of Use by Licensee under Section 10.2 or by Penn under Sections 10.3 or 10.4, Licensee agrees [*].Article 11â€‹ADDITIONAL PROVISIONS11.1Relationship of the Parties.Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. The Parties are independent contractors and at no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party.11.2Expenses.Except as otherwise provided in this Agreement, each Party shall pay its own expenses and costs incidental to the preparation of this Agreement and to the consummation of the transactions contemplated hereby.11.3Third Party Beneficiary.The Parties agree that each Sublicensee is a third party beneficiary of this Agreement with respect to Section 10.4.3.11.4Use of Names.Licensee, its Affiliates and Sublicensees may not use the name, logo, seal, trademark, or service mark (including any adaptation of them) of Penn or any Penn school, organization, employee, student or representative, without the prior written consent of Penn. Notwithstanding the foregoing, Licensee may use the name of Penn in a non-misleading and factual manner solely in (a) executive summaries, business plans, offering memoranda and other similar documents used by Licensee for the purpose of raising financing for the operations of Licensee as related to Licensed Product, or entering into commercial contracts with Third Parties, but in such case only to the extent necessary to inform a reader that the Penn Patent Rights, DRG Patent Rights, DRG Know-How and/or Licensed Know-How (subject to the provisions of Article 7) has been licensed by Licensee from Penn, and/or that Licensee collaborated with Penn on the Research Programs, and to inform a reader of the identity and published credentials of inventors of intellectual property, and (b) any securities reports required to be filed with the Securities and Exchange Commission. 38â€Œâ€‹â€‹11.5No Discrimination.Neither Penn nor Licensee will discriminate against any employee or applicant for employment because of race, color, sex, sexual or affectional preference, age, religion, national or ethnic origin, handicap, or veteran status.11.6Successors and Assignment.11.6.1The terms and provisions hereof shall inure to the benefit of, and be binding upon, the Parties and their respective successors and permitted assigns.11.6.2Neither Party may assign or transfer this Agreement or any of such Partyâ€™s rights or obligations created hereunder without the prior written consent of the other Party, provided that: (a) such other Party shall not unreasonably withhold, condition or delay its consent; and (b) either Party may assign this Agreement, without the otherâ€™s consent, to an Affiliate of such Party or to a successor entity by way of merger, acquisition, or the sale of all or substantially all of such Partyâ€™s assets or business to which this Agreement relates; provided, that (i) the assignee shall expressly agree in writing to be bound by such Partyâ€™s obligations and liabilities under this Agreement, and (ii) each Party shall promptly notify the other Party of any assignment or transfer under the provisions of this Section 11.6.11.6.3Any assignment not in accordance with this Section 11.6 shall be void.11.7Further Actions.Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.11.8Entire Agreement of the Parties; Amendments.This Agreement, the Exhibits and Appendices or Schedules hereto, and the Equity Issuance Agreement (â€œTransaction Documentsâ€) constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and, except for [*], such Transaction Documents cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter, including, as of the Second Restatement Date, the First ARCA (and the Original Agreement). No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party. Â 11.9Governing Law.This Agreement shall be governed by and interpreted in accordance with the laws of the Commonwealth of Pennsylvania, excluding application of any conflict of laws principles that would require application of the law of a jurisdiction outside of the Commonwealth of Pennsylvania. 39â€Œâ€‹â€‹11.10Dispute Resolution.If a dispute arises between the Parties concerning this Agreement, then the Parties will confer, as soon as practicable, in an attempt to resolve the dispute; provided, however, that nothing in this Section 11.10 will prohibit either Party from (a) [*] or (b) [*]. In addition, in the event of a dispute regarding the interpretation of this Agreement, or whether a Party has committed and/or cured a material breach of this Agreement (for purposes of the other Partyâ€™s termination rights under Article 10), if the dispute is not resolved within [*] under the first sentence of this Section 11.10, then: (i) upon either Partyâ€™s request such dispute will be escalated to Licenseeâ€™s Chief Executive Officer and Pennâ€™s Dean of Medicine or his designee, for discussion in good faith in an effort to resolve such dispute; and (ii) if such dispute remains unresolved another [*] following such escalation, then either Party shall be free to bring any action in, the state and Federal courts located in the Eastern District of Pennsylvania.11.11Notices and Deliveries.Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and directed to a Party at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party. A notice will be deemed received: if delivered personally, on the date of delivery; if mailed, five (5) days after deposit in the United States mail; if sent via courier, one (1) business day after deposit with the courier service; or if sent via facsimile, upon receipt of confirmation of transmission provided that a confirming copy of such notice is sent by certified mail, postage prepaid, return receipt requested.For Pennwith a copy to:â€‹â€‹Penn Center for InnovationUniversity of Pennsylvania3600 Civic Center Rd. 9th FloorPhiladelphia, PA 19104Attention: Executive DirectorUniversity of Pennsylvania Office of General Counsel133 South 36th Street, Suite 300Philadelphia, PA 19104-3246 Attention: General Counselâ€‹â€‹For Licensee:â€‹â€‹Passage Bio1 Commerce Square, 39th Floor Philadelphia, PA 19103Attention: Chief Executive OfficerPassage Bio1 Commerce Square, 39th FloorPhiladelphia, PA 19103Attention: General Counselâ€‹â€‹11.12Waiver.A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. Except as otherwise provided herein, all rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party. 40â€Œâ€‹â€‹11.13Severability.When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Law, but if any provision of this Agreement is held to be prohibited by or invalid under Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.11.14Interpretation.The words â€œinclude,â€ â€œincludesâ€ and â€œincludingâ€ shall be deemed to be followed by the phrase â€œwithout limitation.â€ All references herein to Articles, Sections, Schedules and Exhibits shall be deemed references to Articles and Sections of, Schedules and Exhibits to, this Agreement unless the context shall otherwise require. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with GAAP, as in effect from time to time. Unless the context otherwise requires, countries shall include territories. References to any specific Law or article, section or other division thereof, shall be deemed to include the then-current amendments or any replacement Law thereto.11.15Counterparts.This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.[SIGNATURE PAGE FOLLOWS]â€‹â€‹ 41â€Œâ€‹â€‹IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this Agreement as of the Second Restatement Date.THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIAPASSAGE BIO, INC.â€‹â€‹â€‹â€‹By:/s/ John Swartleyâ€‹ â€‹â€‹ â€‹â€‹ â€‹â€‹By:/s/ Will Chouâ€‹ â€‹â€‹â€‹ â€‹â€‹â€‹ â€‹â€‹â€‹ â€‹Name:John S. Swartley, MBA, PhDName:Will Chou, M.D.Title:Chief Innovation Officer University of Pennsylvaniaâ€‹Title:Chief Executive Officerâ€‹â€‹â€‹Signature Page to Second Amended and Restated Research, Collaboration & License Agreementâ€‹â€‹Exhibit APenn Patent Rights A[*]â€‹â€‹â€‹â€‹â€‹Exhibit BPenn Patent Rights B[*]â€‹â€‹ â€‹ â€‹Œâ€‹â€‹â€‹Exhibit CExcluded CNS Indications[*]â€‹â€‹ â€‹Œâ€‹â€‹â€‹Exhibit DSpecified Obligations[*]â€‹â€‹â€‹â€‹â€‹Exhibit EForm of SDR Report[*]â€‹â€‹â€‹â€‹â€‹Exhibit FForm of Financial Report[*]â€‹â€‹â€‹â€‹â€‹Exhibit GDRG Patent Rights[*]â€‹â€‹â€‹â€‹â€‹Exhibit HDiscovery Patent Rights[*]â€‹â€‹â€‹â€‹â€‹Exhibit ISpecified Licensed Products[*]â€‹â€‹â€‹â€‹â€‹Exhibit JManufacturing Patent Rights[*]â€‹â€‹Exhibit 31.1â€‹CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OFTHE SECURITIES EXCHANGE ACT OF 1934,AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002I, William Chou, certify that:1.I have reviewed this Quarterly Report on Form 10-Q of Passage Bio, 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 registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and5.The registrantâ€™s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™s ability to record, process, summarize and report financial information; andb.any fraud, whether or not material, that involves management or other employees who have a significant role in the registrantâ€™s internal control over financial reporting. â€‹â€‹â€‹â€‹Date: November 13, 2024â€‹â€‹â€‹â€‹/s/ William ChouWilliam ChouPresident and Chief Executive Officer(Principal Executive Officer)â€‹â€‹â€‹Exhibit 31.2â€‹CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OFTHE SECURITIES EXCHANGE ACT OF 1934,AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002I, Kathleen Borthwick, certify that:1.I have reviewed this Quarterly Report on Form 10-Q of Passage Bio, 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 registrantâ€™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 registrantâ€™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 registrantâ€™s internal control over financial reporting that occurred during the registrantâ€™s most recent fiscal quarter (the registrantâ€™s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrantâ€™s internal control over financial reporting; and5.The registrantâ€™s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrantâ€™s auditors and the audit committee of the registrantâ€™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 registrantâ€™s ability to record, process, summarize and report financial information; andb.any fraud, whether or not material, that involves management or other employees who have a significant role in the registrantâ€™s internal control over financial reporting. â€‹â€‹â€‹â€‹Date: November 13, 2024â€‹â€‹â€‹/s/ Kathleen BorthwickKathleen BorthwickChief Financial Officer(Principal Financial Officer and Principal Accounting Officer)â€‹â€‹â€‹Exhibit 32.1â€‹CERTIFICATION PURSUANT TO18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002I, William Chou, President and Chief Executive Officer of Passage Bio, Inc. (the â€œCompanyâ€), do hereby certify, pursuant to 18 U.S.C. SectionÂ 1350, as adopted pursuant to SectionÂ 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:1.Â Â Â Â Â Â Â Â Â Â Â Â the Quarterly Report on FormÂ 10-QÂ of the Company for the fiscal quarter ended September 30, 2024 (the â€œReportâ€) fully complies with the requirements of SectionÂ 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and2.Â Â Â Â Â Â Â Â Â Â Â Â the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.â€‹â€‹â€‹Dated: November 13, 2024Â /s/William ChouÂ Â William Chouâ€‹President and Chief Executive Officer Â Â (Principal Executive Officer)â€‹â€‹â€‹Exhibit 32.2â€‹CERTIFICATION PURSUANT TO18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TOSECTION 906 OF THE SARBANES-OXLEY ACT OF 2002I, Kathleen Borthwick, Chief Financial Officer of Passage Bio, Inc. (the â€œCompanyâ€), do hereby certify, pursuant to 18 U.S.C. SectionÂ 1350, as adopted pursuant to SectionÂ 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:1.Â Â Â Â Â Â Â Â Â Â Â Â the Quarterly Report on FormÂ 10-QÂ of the Company for the fiscal quarter ended September 30, 2024 (the â€œReportâ€) fully complies with the requirements of SectionÂ 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and2.Â Â Â Â Â Â Â Â Â Â Â Â the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.â€‹â€‹â€‹Dated: November 13, 2024/s/Kathleen BorthwickKathleen BorthwickChief Financial Officer(Principal Financial Officer and Principal Accounting Officer)â€‹â€‹