

University Startup Basic Outlicensing Template (US-BOLT) – Life Science edition

INTRODUCTION

Beginning in Spring 2020, the below listed academic institutions, investors and law firms have been working together to create a “representative” term sheet that an investor and an academic institution might use to begin discussions around launching a life science startup. The objective was to create a *reasonable* approach, with terms and clauses that *most* parties could use in *most* situations. Since that time, the creators have embodied those principles into this non-binding term sheet template, with representative clauses, which can be downloaded and used freely by any parties that wish to do so. Through these efforts, we hope to significantly reduce the time spent negotiating these deals across the whole early-stage life science industry, which could lead to therapeutics, diagnostics, and medical devices reaching the market months or years earlier, with the resulting benefit to patients worldwide.

One important note: we say “representative” above because the great majority of the terms herein would be considered reasonable by parties on both sides, and hence we anticipate that in many situations this term sheet could be used without significant further edits. However, it should be noted that any given institution or investor may have certain preferred approaches or policies about which they may feel strongly. For instance, some institutions have strong feelings in particular around sublicensing income, reservation of rights, or access to future improvements. And some investors have equally strong feelings about equity, success fees or board observer seats. Unfortunately, it would have been impossible to create a single document which incorporated all variations. Accordingly, some of the contributing entities, and other parties as well, may need to use alternative approaches to those in the term sheet template, even if they have approved the general approach espoused herein. Hence, nothing in these documents should be seen as binding any of the undersigned, but rather as a reasonable approach overall for most situations. In that spirit, we hope you find this term sheet useful. Over the next few months, we hope to release a full license agreement template, based on this term sheet. If you have any questions, comments or concerns, or would like to have your institution added to the “Endorsed By” line, please email techtransferVCstartups@gmail.com.

Best wishes, from the creators of this document (contact person with their entity in parentheses):

- Academic institutions: Orin Herskowitz, Ofra Weinberger, Melissa Cohen (Columbia), Robin Rasor (Duke), Isaac Kohlberg (Harvard), Steve Kousouris (Johns Hopkins), Lauren Foster (MIT), Karin Immergluck (Stanford), Teri Willey (Indiana University), Rick Brandon (University of Michigan), Ian McClure (University of Kentucky), John Swartley (University of Pennsylvania), and Jon Soderstrom (Yale)
- Venture capital firms: Galya Blachman, Jessica Alfano and Deb Palestrant (5AM Ventures), Kevin Bitterman (Atlas), Deirdre Cunnane (Omega Funds), Kirsten Leute and Bill Harrington (OUP), Amy Schulman and Alexandra Cantley (Polaris), Sarah Reed, Nadim Shohdy and Josh Resnick (RA Capital), and Cami Samuels (Venrock)
- Law firms: Geoff Spolyar (Cooley), Sarah Solomon (Goodwin), and Kathy Ku (Wilson Sonsini)

Additional Endorsements at launch (if you would like to add your name please email: techtransferVCstartups@gmail.com):

Reviewed and Endorsed by Tech Transfer Offices of the following Universities:

- California Institute of Technology (Caltech)
- Columbia
- Cornell University
- Duke

- Harvard
- Indiana University
- Johns Hopkins
- MIT
- National Jewish Health
- New York University
- Puerto Rico Science, Technology and Research Trust
- Stanford
- University of Kentucky
- University of Michigan
- University of Minnesota
- University of Pennsylvania
- University of Texas Austin
- University of Virginia
- UWM Research Foundation
- Vanderbilt University
- Wisconsin Alumni Research Foundation (WARF)
- Yale

Venture Capital Firms

- 5AM Ventures
- Atlas
- F-Prime
- Medical Excellence Capital
- Omega Funds
- OUP
- Polaris
- RA Capital
- RTW Investments
- Smarthealth Catalyzer
- Sofinnova Investments
- Third Rock Ventures
- Digitalis Ventures

University Startup Basic Outlicense Template – Life Science edition

Capitalized terms that are not defined in the body of the Term Sheet are defined in the “Defined Terms” section at the end of the Term Sheet.

Date	
Licensor¹	
Licensee	[] and/or its Affiliate(s). The term “Licensee” will only include Affiliate(s) to the extent that the License is assigned to such Affiliate or an Affiliate is granted a Sublicense.
Territory	“ Territory ” means worldwide.
Field of Use	[any and all uses [in humans]] ²
Term	The License Agreement will begin on the Effective Date and will expire upon expiration of the last remaining Royalty Term, unless earlier terminated in accordance with the termination provisions. On a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of the applicable Royalty Term, Licensee will have a fully paid-up perpetual license to Licensed Know-How for such Licensed Product in such country (“country” shall also be deemed to refer to territories).
Patent Rights	means Licensor’s rights under the following: <ul style="list-style-type: none"> (a) the patents and patent applications listed in <u>Exhibit A</u>; (b) any non-provisional patent applications that claim priority to any provisional patent applications listed in <u>Exhibit A</u>; (c) any foreign patent applications, foreign patents or related foreign patent documents that claim priority to a patent or patent application included in (a) or (b) above; (d) any divisionals and continuations of patents or patent applications included in (a), (b), or (c) above (but not continuations-in-part, except as provided in (f) below); (e) any patents, reissues, re-examinations, renewals, substitutions, and extensions issuing from the patent specification of any of the preceding; and (f) any claims of continuation-in-part applications that claim priority to the U.S. patent applications listed in <u>Exhibit A</u>, but only to the extent such claims are directed specifically to subject matter described in at least one of the patents or patent

¹ If there is an Inter-Institutional Agreement or joint ownership of the licensed technology, include a description here.

² Therapeutics should generally be licensed for all uses, to avoid the risk of another licensee’s using the Licensed Technology for something else and obtaining data that may jeopardize approval by the FDA of Licensee’s products.

	<p>applications identified in (a)-(e) above that meet the written description requirements of the first paragraph of 35 U.S.C. Section 112.³</p> <p>Patent Rights do not include any inventions conceived (as determined under U.S. patent law) after the Effective Date, provided that to the extent a Patent Right is an Improvement, such Improvement will be added to <u>Exhibit A</u> by way of amendment.</p>
License to Improvements⁴	<p>Licensor shall disclose to Licensee all Improvements made in the laboratory of [Principal Investigator] within [1-3] years of the Effective Date and disclosed to Licensor by the [Principal Investigator].</p> <p>Patentable Improvements shall be added by amendment to the list of Patent Rights in <u>Exhibit A</u> of the License Agreement and Improvements that are not patentable will be considered Licensed Know-How and shall be added to <u>Exhibit B</u> of the License Agreement [in both cases by mutual agreement of the parties] and shall be licensed on the same terms of the License, with the option of minor additional economic terms (e.g., an upfront fee).</p> <p>(Note: add this language where an SRA is executed in conjunction with the License:) In addition, any Improvements that are developed under the SRA in the laboratory of [name the Principal Investigator] shall be included in the License as Patent Rights.)</p> <p>“Improvement” means any invention, patentable or otherwise, conceived under the direction of the [Principal Investigator] where the invention is (a) not encumbered by any third party rights, (b) has been disclosed to Licensor’s technology licensing office, and (c) for patentable Improvements, would necessarily infringe at least one Valid Claim in the Field of Use.</p>
License	<p>Licensor grants to Licensee an exclusive license to the Patent Rights, and a non-exclusive license to use Licensed Know-How, to research, discover, develop, manufacture/make, have made, use, market, sell, offer to sell, have sold, import, export, distribute, rent, license to end-users or lease Licensed Products in the Field of Use and the Territory.⁵</p>
Sublicensing Rights / Requirements	<p>The License Agreement shall include the right to grant Sublicenses through multiple⁶ tiers of Sublicensees. Within 30 days after execution of each Sublicense, Licensee will furnish Licensor a complete copy of the Sublicense and any amendments to the Sublicense; provided, however, that Licensee has the right to redact any portion of the Sublicense that does not relate to</p>

³ The intention is to cover inventions that are disclosed in the original application, but where the original application did not include sufficient disclosure for enablement purposes.

⁴ Where Licensee seeks to include improvements under the license, careful attention must be given to Licensor’s tax risks (e.g., Internal Revenue Procedure Ruling 97-14 or successor IRS guidance; also consider ramifications of state tax law and Bayh Dole), potential conflict of interest issues, and policies on licensing future IP. Some universities will seek to include improvements by way of subsequent amendments rather than as a matter of initial right.

⁵ This term sheet contemplates a license to patents and know-how. If Licensed Know-how is not part of the transaction, the provisions of the term sheet will need to be revised accordingly.

⁶ In the event Sublicensing is permitted through only a specified number of tiers, then provide that (a) Licensor shall not unreasonably withhold consent to additional tiers of Sublicenses and (b) in any event, if any Sublicensee is a Significant Partner, the Significant Partner has the right to license through multiple tiers. **“Significant Partner”** means a company that has a market capitalization of at least \$1 billion.

	<p>the Licensed Products, Patent Rights or Licensed Know-How. Licensee will not be required to provide Subcontracts to Licensor.</p> <p>Licensee will require that all Sublicenses be consistent with the terms and conditions of the License Agreement, including e.g., the following duties: to keep records; to properly mark Licensed Products with patent numbers; to defend, hold harmless, and indemnify Licensor; to maintain insurance; to restrict the use of Licensor's name and to control exports. Sublicensing is permitted provided that Licensee has exclusive Patent Rights under the License Agreement, Licensed Know-How is only being sublicensed in connection with Licensed Patent Rights, and that Licensee is not in material breach of the License Agreement.</p>
<p>Survival of Sublicenses</p>	<p>If the License Agreement terminates for any reason, Licensor will provide to each Sublicensee the right to enter into a license of the Licensed Technology in the applicable Sublicense directly with Licensor, under the same terms and conditions as the License Agreement (as reasonably applied to such Licensed Technology); provided that (a) Licensor and Sublicensee will discuss in good faith any appropriate modifications to such terms and conditions and (b) Licensor is not obligated to enter into a license agreement having a scope of Licensed Technology, Field of Use, Territory, or other obligation on the part of Licensor that would exceed those in the applicable Sublicense.</p> <p>Licensor's obligation above will apply only if (a) Licensor is legally, contractually, and per its policies permitted to enter into such license at the time; (b) Sublicensee provides written notice to both Licensor and Licensee within 90 days after such termination of its desire for such discussions, and Licensee does not dispute the termination; (c) Sublicensee is not an Affiliate of Licensee; and (d) Sublicensee is not in material breach of the Sublicense [in the two year period prior to the License Agreement termination]. The Sublicense shall not be terminated during the 90 day notice period and the negotiation period between Licensor and Sublicensee.</p>
<p>Subcontracts</p>	<p>Licensee may engage a subcontractor to perform, on behalf of Licensee, research, development, and manufacturing services under the License, provided that (i) any subcontract will not relieve Licensee from any of its obligations under the License; (ii) any act or omission by a subcontractor shall be deemed an act or omission of Licensee; (iii) any subcontract provides for the automatic assignment to Licensee of any and all intellectual property generated by the subcontractor, its employees, and consultants in the course of performing the subcontracted services to Licensee (other than with respect to intellectual property generated that relates to such subcontractor's platform or background intellectual property, ownership of which may remain with such subcontractor); and (iv) Licensee shall be responsible for each of its subcontractors complying with all applicable obligations of Licensee under the License. A subcontractor that Licensee has engaged through an agreement complying with the terms above shall not be deemed to be a Sublicensee under the License, regardless of whether such subcontract includes a grant of a sublicense under any Patent Rights or Licensed Know-How.</p>
<p>License Issue Fee</p>	<p>Licensee shall pay an up-front fee of \$___ within [x] days of the Effective Date.⁷</p>

⁷ The amount of the up-front fee may be impacted by the patent expenses to be reimbursed, particularly where they are significant.

<p>[Equity]⁸</p>	<p>Licensee shall issue to Licensor⁹ shares of its common stock representing [x]% on a Fully Diluted Basis [[at the Effective Date] or [at the closing of Licensee’s next round of equity financing]].¹⁰</p> <p>“Fully-Diluted Basis” means the total number of shares of Licensee’s issued and outstanding common stock, assuming (a) the conversion of all issued and outstanding securities convertible into common stock; (b) the exercise of all issued and outstanding warrants or options, regardless of whether then exercisable; and (c) the issuance, grant, and exercise of all securities reserved for issuance pursuant to any Licensee stock or stock option plan then in effect.</p> <p><u>Anti-Dilution:</u> Licensee will issue Licensor, without further consideration, additional shares of common stock as is necessary to ensure that the number of shares issued to Licensor do not represent less than x% of the shares issued and outstanding on a Fully-Diluted Basis. This anti-dilution protection will continue until an amount of at least \$X,000,000, when aggregated with prior closings, has been raised by Licensee in bona fide financings through the sale of securities or by conversion of instruments convertible into equity (“Dilution Cap”). If the Dilution Cap is reached or exceeded during a specific round of funding, anti-dilution protection [will] [will not] extend to the total amount of funding raised through the closing of that specific round of funding.¹¹</p> <p><u>Preemptive Rights:</u> If Licensee proposes to sell any equity securities or securities that are convertible into equity securities, Licensor and/or its Assignee may purchase up to [[their pro rata] or [x%]]¹² of the securities issued in each financing on the same terms and conditions as are offered to the other purchasers in each such financing. Licensee will provide [x] days advance written notice of each such financing, including reasonable detail regarding the terms and purchasers in the financing. “Assignee” means (a) [insert name of entity to which Licensor’s preemptive rights may be assigned] or (b) any entity that is controlled by Licensor.</p>
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⁸ Universities differ in their approaches: some may not ask for either equity or a success fee, some may ask for one or the other, and some may ask for both. Licensee and their venture capital investors may advocate for a success fee rather than equity (but not both), as an approach which is both simpler and avoids any issues under Licensor’s conflict of interest policies. Success fees can take the form of (a) a percentage of the [upfront] acquisition proceeds in the event Licensee is acquired; (b) a percentage of Licensee’s market capitalization for x days trailing post-IPO lockup; (c) a fixed dollar amount upon either of those events; or (d) a fixed dollar amount upon Licensee achieving and maintaining a valuation above a certain threshold in the public markets.

⁹ Some universities may have a separate entity that holds equity in startups on behalf of the university, in which case such entity should be named here instead of the Licensor.

¹⁰ The parties will discuss whether a minimum financing size should be stipulated and the mechanics for a multi-tranche financing round (e.g., an allocable portion of the university’s equity is metered in at each tranche).

¹¹ Some universities will delay issuance of all equity shares until the Dilution Cap has been met.

¹² Few universities have the financial flexibility to participate in these investments within the time frame required. In participating in an equity financing, they will be subject to terms that may be unattractive to them, e.g., pay-to-play (see [NVCA Model Documents](#) for details on Preferred Stock financing terms.) Accordingly, many universities have entered into agreements to transfer any such preemptive rights to Osage University Partners. Venture Capital investors may find this request difficult to accommodate in their standard syndicated financing rounds.

Development Milestone Payments¹³	<p>Each of the following payments (each a “Development Milestone Payment”) will be due upon achieving the indicated milestone (each such milestone, a “Development Milestone” for [each Licensed Product] [the first Licensed Product] [the first [2][3] Licensed Products]).¹⁴ Licensee shall make each such payment irrespective of whether the associated Development Milestone was reached by Licensee itself, by a Sublicensee and/or by a third party acting on behalf of Licensee or a Sublicensee.</p> <p><i>[Examples of typical Development Milestones]¹⁵:</i></p> <ul style="list-style-type: none"> • [First/third/fifth]¹⁶ subject dosed in Phase [1/2/3] clinical trial: [\$_____] • Submission of the first IND for a Licensed Product: [\$_____] • FDA approval of a Licensed Product: [\$_____] • First Commercial Sale of a Licensed Product: [\$_____]
Royalty Rate¹⁷	<p>For Patent Products, Licensee shall pay Licensor x% of Net Sales, with [50]% reduction for Patent Products that are no longer Covered by a Valid Claim [and are no longer under regulatory exclusivity], but are Covered by Licensed Know-How. For Know-How Products, Licensee shall pay Licensor [½]x% of Net Sales.</p>
Net Sales	<p>means, with respect to a Licensed Product, for any period, the total amount billed or invoiced on sales of such Licensed Product during such period by the Selling Party in the Territory to third parties (including third party wholesalers and Third Party Distributors), in bona fide arm’s length transactions, less the following documented deductions¹⁸, and in each case related specifically (or reasonably allocated by such Selling Party in accordance with its standard policies and procedures consistently applied across its products) to the Licensed Product, and not otherwise recovered by or reimbursed to the Selling Party:</p> <ul style="list-style-type: none"> (a) trade, cash and quantity discounts, charge-back payments, and rebates actually granted to trade customers, managed health care organizations, pharmaceutical benefit managers, group purchasing organizations, and national, state, or local governments; (b) credits, rebates, or allowances actually allowed upon prompt payment or on account of claims, damaged goods, rejections, or returns of such Licensed Product, including in connection with recalls and retroactive price reductions; (c) taxes to the extent included in the gross amount invoiced (excluding income or franchise taxes of any kind), duties, tariffs, mandated contribution, or other governmental charges levied on the sale of such Licensed Product, including

¹³ Large milestone payments can be difficult for even well-funded Licensees if Licensee has not yet partnered with or been acquired by Big Pharma. Accordingly, Licensor may consider mechanisms to reduce the burden for Licensee before it has partnered or been acquired, e.g., (a) milestone payments start low but increase on partnering/acquisition or (b) x% of milestone payments can be deferred until Licensee is partnered/acquired.

¹⁴ For platform technologies, there will often be a cap on the number of products for which these milestones apply.

¹⁵ The number and type of milestones vary in each deal.

¹⁶ In selecting whether to use first, third or fifth subject, consider the modality of the product as well as the anticipated development timeline. The term “subject” is used instead of “patient” because all participants are subjects of a clinical trial but may not be patients.

¹⁷ Tiered royalty rates may be negotiated.

¹⁸ The deductions detailed here represent a tailored set of the typical deductions included in Big Pharma licenses, consistent with common commercial practices, in an effort to avoid future renegotiation.

VAT (net of reimbursement of any value added taxes actually received), excise taxes and sales taxes, that the Selling Party allocates to sales of such Licensed Product in accordance with its standard policies and procedures consistently applied across its products, as applicable;

- (d) the portion of administrative fees paid during the relevant time period to group purchasing organizations, pharmaceutical benefit managers or Medicare Prescription Drug Plans relating to such Licensed Product;
- (e) any invoiced amounts from a prior period which are not collected and are written off by the Selling Party, including bad debts (provided that if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales for the period during which it is paid);
- (f) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) to the extent (a) reasonably allocable to sales of such Licensed Product and (b) the Selling Party actually includes such fee as a deduction from gross revenue in its publicly filed financial reports;
- (g) packaging, freight, postage, shipping, transportation, warehousing, handling, export/import and insurance charges, in each case, actually allowed or paid for delivery of such Licensed Product, and any customary payments with respect to such Licensed Product actually made to wholesalers or other Distributors, in each case, actually allowed or paid for distribution and delivery of such Licensed Product, to the extent billed on actual invoices;
- (h) any sales, credits, or allowances given or made with respect to such Licensed Product for wastage replacement; and
- (i) any other similar and customary deductions that are consistent with GAAP as consistently applied by Selling Party to all of its products, but which may not be duplicative of the above deductions.

For Combination Products, Net Sales will be calculated as follows:

- (a) If the Licensed Product and all Other Components of the Combination Product were sold separately during the same or immediately preceding calendar quarter, the proration factor will be determined by the formula $[A / (A+B)]$, where A is the weighted average¹⁹ invoice price of all Licensed Product components during such period when sold separately from the Other Component(s), and B is the weighted average gross invoice price of the Other Components during such period when sold separately from the Licensed Product (as applicable);
- (b) If the Licensed Product components containing only the Licensed Compound as its Active Ingredient are sold separately from the Other Components, but the Other Components in such Combination Product are not sold separately, then the proration factor will be determined by the formula $[A / C]$, where A is the average gross sales price of all Licensed Product components containing only the Licensed Compound as its Active Ingredient during such period when sold separately from the Other Components, and C is the average gross sales price of the Combination Product during such period;

¹⁹ "Weighted average" is used to take into account the volume of sales at different prices. For example, products sold for \$5 to one customer and \$10 to another would have a flat average of \$7.50, but if most products are sold at \$10, the weighted average would capture that.

- (c) If the Licensed Product components containing only the Licensed Compound as its Active Ingredient are not sold separately from the Other Components, but the Other Components in such Combination Product are sold separately, then the proration factor will be determined by the formula $[(C - B) / C]$, where B is the average gross sales price of the Other Components included in such Combination Product if sold separately from the other component(s), and C is the average gross sales price of the Combination Product during such period; or
- (d) If neither the Licensed Compound nor the Other Components included in the Combination Product were sold or provided separately during the relevant period, then the proration factor will be mutually agreed upon by the parties in good faith based on the relative value contributed by each component and, to the extent the parties are unable to establish such proration factor, then such proration factor will be established by Standard Dispute Resolution.
- (e) In the event that such separate sales were not made or performed during the immediately preceding calendar year (“CY”), then the invoiced amounts for the Combination Product for purposes of calculating Net Sales will be multiplied by the fraction $C / (C + D)$, where C is the average fully burdened cost of manufacture of the Licensed Products during the immediately preceding CY and D is the average fully burdened cost of manufacture of the additional items during the immediately preceding CY, in each case calculated in accordance with GAAP.

Any allocation of revenue from the sale or other disposition of Combination Products, or any allocation of the costs of manufacture, shall be done in good faith, and will take into consideration revenue recognition guidance under GAAP which is applicable to multiple-deliverable revenue arrangements.

All allocations of discounts, allowance, credits, rebates and other deductions must be reasonable. Any amounts received or invoiced by a Selling Party will be accounted for only once. For purposes of determining Net Sales, a Licensed Product will be deemed to be sold when recorded as a sale by Selling Party in accordance with GAAP.

Amounts received or invoiced by Licensee or a Sublicensee for the sale of a Licensed Product among Licensee or a Sublicensee will not be included in the computation of Net Sales, unless the purchasing entity is the end-user of such Licensed Product.

Net Sales will exclude any Licensed Product transferred or disposed of as samples or for clinical trials or at or below costs of goods therefor for any so-called treatment investigational new drug sales, named patient sales, expanded access program, compassionate or emergency use sales or pre-license sales made for non-commercial, compassionate purpose, or any indigent program or promotional or educational purposes; in each case with respect to such Licensed Product and are reported on the royalty report for such period when such Licensed Products are so transferred or disposed of.

Net Sales will be calculated in accordance with the standard internal policies and procedures of the Selling Party.

For purposes of calculating Net Sales, all Net Sales shall be converted into U.S. dollars.

“Royalty Term”	means, on a Licensed Product-by-Licensed Product and country-by-country basis, the royalty term will commence on the First Commercial Sale of a Licensed Product in any country and continue until the latest of (a) the date on which such Licensed Product is no longer Covered by a Valid Claim in the country in which the manufacture or sale occurs; (b) the expiration of Regulatory Exclusivity for such Licensed Product in the country in which the sale occurs; ²⁰ and (c) the [x] year anniversary of the First Commercial Sale of such Licensed Product in the country in which the sale occurs.
Minimum Annual Royalty	Licensee shall pay Licensor Minimum Annual Royalties as set forth below. Earned royalties paid during a given CY may be used as credit against the Minimum Annual Royalty due for that same CY, but cannot be used as credit against a Minimum Annual Royalty obligation owed for any other CY. <ul style="list-style-type: none"> • [First full CY] after Effective Date: [\$ _____] • [Second through fourth full CYs after Effective Date]: [\$ _____] • [Fifth full CY after Effective Date and each CY thereafter until First Commercial Sale]: [\$ _____] • [First CY after First Commercial Sale and each CY thereafter]: [\$ _____)]²¹
Royalty Stacking²²	Licensee will be entitled to deduct, from the cumulative royalties otherwise due Licensor in respect of Net Sales of Licensed Products, [X%] ²³ of all such royalties paid or payable by Selling Party(ies) to one or more third parties in respect of such Licensed Products if, in the absence of a license, sublicense, acquisition or access to a third party’s intellectual property rights, the researching, discovering, developing, manufacturing/making, having made, using, marketing, selling, offering to sell, having sold, importing, exporting, distributing, renting, licensing to end-users or leasing of a Licensed Product would or is likely to infringe or misappropriate such intellectual property rights. In no event will such deduction reduce any royalty payments to be made by Licensee by more than [X%] for any calendar quarter; and provided, further, that any reduction, or portion thereof, may be carried forward for use in a future calendar quarter. With respect to any third party exclusive licensors, the foregoing royalty stacking provisions will only apply in the event such third party exclusive licensors receiving royalties of [x]%] are also subject to similar royalty stacking provisions. ²⁴

²⁰ In considering whether Regulatory Exclusivity will be included as a component of the Royalty Term, consider whether subsection (c) will in any case run longer than any Regulatory Exclusivity (in which case it may not be necessary). Further, consider whether Regulatory Exclusivity should be included in the Royalty Term if the Licensed Technology does not support Regulatory Exclusivity.

²¹ The Minimum Annual Royalty is intended to incent Licensee to diligently develop the technology. The number of years during which Annual Minimum Royalty is due reflects the anticipated time to first commercial sale.

²² The parties may consider eliminating royalty stacking entirely in favor of a lower royalty rate.

²³ A higher deduction may be negotiated if the total royalty burden is higher than 80% of the total royalties that Licensee would receive from sublicensees. Additionally, the royalty offset may include all payments, rather than just royalties.

²⁴ It is quite common for licenses that have a sufficiently low royalty rate to not include anti-stacking provisions; thus, by way of example, if a third party licensor is receiving a low royalty, such royalty payable to such third party licensor would be included within the royalty stack, regardless of whether the agreement with such third party licensor includes an anti-stacking provision. This limitation only applies to exclusive licensors of intellectual property rights (not non-exclusive licensors).

<p>Sublicensing Consideration²⁵</p>	<p>Licensee shall pay to Licensor a portion of all Sublicensing Income as follows:²⁶</p> <ul style="list-style-type: none"> • W% of Sublicensing Income received as the result of any Sublicense entered into prior to [event or date X]; • X% of Sublicensing Income received as the result of any Sublicense entered into after [event or date X] but before [event or date Y]; • Y% of Sublicensing Income received as the result of any Sublicense entered into after [event or date Y] but prior to [event or date Z]; and • Z% of Sublicensing Income received as the result of any Sublicense entered thereafter. <p>Licensee may apportion a commercially reasonable percentage of Sublicensing Income between the Patent Rights and patent rights owned or controlled by Licensee and that are included in the same Sublicense, provided that (a) Licensee provides Licensor with reasonably detailed information on the apportionment and justification no later than 60 days prior to the due date for amounts due and (b) Licensee and Licensor agree on the apportionment. If Licensee and Licensor cannot agree on the apportionment, the parties shall use Standard Dispute Resolution.</p>
<p>Diligence Milestones</p>	<p>Licensee shall use Commercially Reasonable Efforts to develop at least one Licensed Product in the Territory and commercialize such Licensed Product following regulatory approval.²⁷</p> <p>In addition, Licensee (either itself or through the acts of a Sublicensee) is required to achieve the following due diligence milestones (the “Diligence Milestone”) by the dates set forth below (the “Achievement Date”):</p> <p><i>[Examples of Diligence Milestones:]</i></p> <ul style="list-style-type: none"> • Obtaining financing in an amount of at least [\$] by [DATE] • Nomination of a development candidate by [DATE] • Initiation of GLP toxicity studies by [DATE] • Submission of the first IND for a Licensed Product by [DATE] • First subject dosed in Phase 1 clinical trial by [DATE]
<p>Deferral of Diligence Milestones</p>	<p>Licensor acknowledges that due to long development times, scientific, potential safety and development hurdles and challenges and regulatory requirements and processes associated with Licensee’s industry, Licensee may be unable to achieve a particular Diligence Milestone by a relevant Achievement Date. Licensee will notify Licensor in writing in advance of any such anticipated delay, and as long as Licensee is fulfilling its obligations of Commercially Reasonable Efforts, the parties will negotiate in good faith an extension of the relevant Achievement Date upon the payment of a fee (the “Extension Fee”) equal to [\$x/x% of the relevant Development Milestone Payment], which extension Licensee must exercise no later than [x</p>

²⁵ The parties may consider eliminating sublicensing consideration provisions entirely in favor of a higher royalty rate.

²⁶ Alternatively, Licensor may negotiate a flat, but reduced, rate. The tiers are meant to reflect development stage of the Licensed Product, and will often match the diligence milestone tiers.

²⁷ The number and type of diligence milestones vary in each deal and should be based upon the development plan provided by Licensee. If Big Pharma takes a sublicense, they will typically ask for a revision of the diligence milestone terms - e.g., they may agree to use Commercially Reasonable Efforts to develop a Licensed Product, but will ask to remove specific diligence milestones, and Licensors will typically approve.

	days] before the relevant Achievement Date. [Licensee may extend each Diligence Milestone as set forth above only [once/twice]]. ²⁸
Patent Prosecution	<p>Licensor will have the right to control the preparation, filing, prosecution and maintenance of the Patent Rights, reexaminations, interferences, oppositions, and any other <i>ex parte</i> or <i>inter partes</i> matters (e.g., <i>inter partes</i> reviews) originating or conducted in a patent office (“Patent Actions”), using outside counsel reasonably satisfactory to Licensee. Licensor will (a) instruct Licensor’s patent counsel to furnish to Licensee copies of material documents relevant to such Patent Actions before any deadlines; (b) allow Licensee a reasonable opportunity to comment on material documents filed with respect to such Patent Actions; and (c) take into reasonable consideration such comments from Licensee. Licensee will, to the fullest extent permitted by law, apply for and prosecute, or support in any reasonable way Licensor’s application for, any reasonable patent term extension for patents included in the Patent Rights.</p> <p>So long as Licensee reimburses Licensor for Patent Costs, Licensor will continue to prosecute and maintain the Patent Rights in the countries selected by Licensee.</p> <p>Subject to the terms of this section, with the consent of Licensor (such consent not to be unreasonably withheld), Licensee has the right, on a country-by-country basis, to elect to not reimburse Licensor for Patent Costs related to a particular Patent Action. If Licensee makes such an election, Licensee will provide reasonable advance notice to Licensor in writing, such notice to be at least 90 days prior to any such Patent Action.²⁹ Upon such notice, such patent application(s) and patent(s) thereafter are and will be excluded from the definition of Patent Rights without further notice. Under such circumstances, Licensor may elect to abandon or continue the prosecution and/or maintenance of such application(s) or patent(s) at its sole or subsequent partner’s expense. If Licensee fails to provide such notice and Licensor incurs Patent Costs in respect of such Patent Action, then Licensee shall be responsible for such Patent Costs.</p>
Patent Expense Reimbursement	<p>Licensee will bear all out-of-pocket costs incurred by Licensor for Patent Actions (“Patent Costs”). Licensee will reimburse Licensor [within 30 days after Licensee’s receipt of an invoice from Licensor] for Patent Costs incurred by Licensor before the Effective Date and during the term of the License Agreement. Alternatively, if Licensor requests, Licensee will pay ongoing Patent Costs in advance or under a reasonable direct billing arrangement with Licensor’s patent counsel.³⁰ Licensor will provide Licensee with documentation of the Patent Costs.</p>
Disclaimer of Warranties and	<p>LICENSED TECHNOLOGY IS PROVIDED BY LICENSOR WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY OF ANY KIND, EXPRESS OR IMPLIED. LICENSOR MAKES NO EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY THAT USE OR COMMERCIALIZATION OF THE</p>

²⁸ Typically universities will be reasonable in extending milestones for a defined period if Licensee provides adequate explanation and is continuing to be diligent in its pursuits, and typically will be open to waiving the fee for the first failure to meet a Diligence Milestone for a valid reason.

²⁹ Under Bayh-Dole, recipients of federal funding are required to provide notice prior to abandoning any U.S. patents or applications.

³⁰ Payment terms will vary depending on the amount to be reimbursed and Licensee’s funding – e.g., if there were high IP costs pre-License, Licensee may work out a payment schedule.

Limitation of Liabilities	<p>PATENT RIGHTS OR LICENSED PRODUCTS OR NON-PATENT TECHNOLOGY WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS.</p> <p>Except as otherwise provided in the License Agreement, the License Agreement does not imply (a) a warranty or representation as to the validity, enforceability, or scope of any Patent Rights; (b) by implication, estoppel or otherwise, any grant of any license under any patents other than the Patent Rights or under any other rights other than the Licensed Know-How of Licensor, regardless of whether such patents or other rights are dominant or subordinate to Patent Rights.</p> <p>In no event will either party be responsible or liable for any indirect, special, incidental, or consequential damages or lost profits or other economic loss or damage regardless of legal or equitable theory. The above limitations on liability apply even if the other party may have been advised of the possibility of such damage.³¹</p>
Indemnification and Insurance³²	
Patent Challenges	<p>Licensee will provide written notice to Licensor at least 90 days before Licensee, or Sublicensee initiates or participates directly or indirectly in a Patent Challenge. Licensee or such Sublicensee will identify all prior art and other evidence material to the Patent Challenge in such written notice. If Licensee or a Sublicensee participates directly or indirectly in a Patent Challenge, the following applies:</p> <ul style="list-style-type: none"> (a) [Licensor has the right to terminate the License Agreement at any time (including after the termination of such Patent Challenge) upon written notice delivered to Licensee, and the License Agreement cure provisions for non-monetary breach will not apply; provided that if a Patent Challenge is initiated by a Sublicensee, Licensor will only be permitted to terminate the License Agreement if, within 30 days following receipt of notice that Sublicensee has initiated a Patent Challenge, Licensee has failed to terminate the Sublicense or Sublicensee has not vacated the Patent Challenge.]³³ OR (a) Licensor will meet with Licensee and any designee of Licensee within three months after such notice from Licensee and at least semi-annually at the request of Licensee, in a good faith effort to resolve any Patent Challenge; (b) during the pendency of such action or proceeding (including any appeals), the applicable royalty rate(s) will increase to double the applicable royalty rate(s); (c) should the outcome of such action or proceeding determine that any such claim challenged by Licensee or a Sublicensee is valid, enforceable, and/or infringed by a Licensed Product, the royalty rate(s) will increase to triple the applicable royalty rate(s);

³¹ The parties may negotiate additional exclusions, and Licensor will be required to follow the policy of its Office of General Counsel in these matters.

³² These provisions are not included in the Term Sheet because each Licensor will be subject to the policies of its Office of General Counsel on these matters, and hence there are no “standard” terms.

³³ Termination may not be enforceable. Licensors may seek meaningful penalties, up to and including termination of the License Agreement, for Licensee’s challenge to their patent position.

	<p>(d) Licensee and any Sublicensee(s) will have no right to recoup any royalties paid before such action or proceeding or during the period in which such action or proceeding is pending (including on appeal), no matter the outcome of such action or proceeding; and</p> <p>(e) Licensee shall pay all reasonable costs and expenses incurred by Licensor (including, but not limited to, Licensor's actual attorneys' fees) in connection with such action or proceeding. Licensor may bill Licensee as frequently as monthly concerning such costs and expenses, and Licensee shall make payment no later than 30 days after receiving an invoice from Licensor. Notwithstanding any other provision of the Agreement, with respect to any such Patent Challenge, Licensor will have full control and authority to defend the Patent Rights in the action or proceeding and will not be required to share any work product concerning such action or proceeding with Licensee or the Sublicensee(s).</p>
Third Party Claim	In the event of a third-party challenge (including <i>inter partes</i> reviews and declaratory judgements) to any of the Licensed Technology, Licensor will have the first right to assume and control the defense of the claim at Licensor's expense. If Licensor fails to assume such defense within 60 days of becoming aware of such challenge, Licensee may assume and control such defense at Licensee's expense. The party controlling the defense may join the other party in any such action if a court of competent jurisdiction determines the other party is an indispensable party to such proceeding and the controlling party shall pay the expenses of the joined party. The party controlling the defense of such legal action will keep the other party reasonably informed of the proceedings and will not settle such action without the prior written consent of the other party, such consent not to be unreasonably withheld.
Patent Enforcement	In the event that either party believes that a third party is infringing or misappropriating any of the Licensed Technology, [Licensee/Licensor] will have the first right to enforce the claim at [Licensee's/Licensor's] expense. If [Licensee/Licensor] fails to initiate such action within 90 days of becoming aware of such infringement or misappropriation, the other party may assume and control such action at the other party's expense. ³⁴ The party controlling the action may require the other party to join in any such action if a court of competent jurisdiction determines the other party is an indispensable party to such proceeding and the controlling party will pay the expenses of the joined party. ³⁵ The party controlling such legal action will keep the other party reasonably informed of the proceedings and will not settle such action without the prior written consent of the other party, such consent not to be unreasonably withheld.
Award Sharing	Any recovery, whether by way of settlement or judgment, from a third party pursuant to a legal proceeding shall first be used to reimburse the initiating party and the non-initiating party for their actual fees, costs and expenses incurred in connection with such proceeding. The initiating party shall divide any remaining amounts from any such settlement or judgment as follows: (i) any recovery reflecting lost profits damages and/or reasonable royalty damages, Licensee retains or receives such recovery, and Licensor retains or receives the amount of royalties due to Licensor had those activities been performed by Licensee, and (ii) all other remaining amounts (including any punitive or exemplary damages) are divided [75%] to the party who initiated or carried on the proceedings and [25%] to the other party.

³⁴ Factors to consider in granting licensor/licensee first right of enforcement: identity of licensor (e.g., big pharma vs. startup; financial stability; level of sophistication; potential infringers; public relations consequences; conflicts of interests for the university)

³⁵ Note that the joined party may require a joint defense and representation agreement.

Unmet Needs³⁶	Licensor would like Licensee to address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics and agricultural technologies for low and middle income countries. If (a) Licensee is unable or unwilling to serve an unmet need for which there is an adequately-resourced company willing to be a Sublicensee, and (b) such potential Sublicensee has provided Licensee with a bona fide, detailed proposal to serve such unmet needs (which Licensee will provide to Licensor), then, unless Licensee can demonstrate to Licensor's reasonable satisfaction that Licensee will serve such unmet need itself or through another third party, Licensee will, at Licensor's request, negotiate in good faith a Sublicense with said potential Sublicensee on reasonable commercial terms. If the Sublicense is not executed within [12] months, then Licensor has the right to grant a license to serve such unmet need exclusively or non-exclusively, on reasonable commercial terms that, in the judgement of Licensee, will not impair its business, and Licensor will notify Licensee of such a license. Notwithstanding the foregoing, in no event will Licensee be compelled to negotiate a Sublicense [within the field of X/for X indications], it being understood and agreed that any such Sublicense would be competitive with or otherwise materially impair Licensee's business as proposed to be conducted.
Institution Reservation of Rights	Without limiting any other rights it may have, Licensor retains, on behalf of itself, the right to practice or have practiced the Patent Rights, and to use or have used the Licensed Know-How for any research, public service, internal (excluding any studies that are required to be reported to the FDA under 21 CFR Parts 58 and/or 312) and/or educational purposes with non-profit research institutions, including sponsored research and collaborations with such non-profit research institutions, and to publish their respective results, and the right to grant the same limited rights to other non-profit research institutions; provided that Licensor will, and will include in any grant of rights to such non-profit research institutions the obligation to, use its best efforts to provide a draft of any planned disclosure from the laboratory of [Principal Investigator] based upon the foregoing to Licensee 45 days in advance, and if Licensee determines new patent applications need to be filed in order to protect the Patent Rights, Licensed Know-How or Improvements, then Licensor agrees to delay such disclosure by an additional delay of 45 days during which the Licensee will prepare and file patent applications with respect to the foregoing at its own cost. The grant of rights to the Licensed Technology is subject to any existing right of the U.S. Government under Title 35, United States Code, Section 200 et seq. and under 37 Code of Federal Regulations, Section 401 et seq., (the (" Bayh Dole Act ") including but not limited to the grant to the U.S. Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced any invention conceived or first actually reduced to practice in the performance of work for or on behalf of the U.S. Government throughout the world. Licensed Products shall be substantially manufactured in the United States to the extent (if at all) required by 35 U.S.C. Section 204.
Audit	No more than once per calendar year, Licensor may appoint a qualified audit firm to audit Licensee's books and records relating to Licensee's payments under the License Agreement. Such audit shall be conducted during normal business hours without unreasonable disruption to Licensee's business, upon 30 days' advance written notice to Licensee. In the event that the audit discloses an underpayment greater than [5-10%] of the amount due, Licensee shall bear the costs of the audit.

³⁶ Some licensees will be reluctant to include this section, depending on their business model.

Board Observer	Up until the Licensee completes its first round of institutional investment [and thereafter by mutual agreement] Licensor may have a Board observer seat.
Assignment	Neither party may assign the License to a third party without the prior consent of the other party; provided that Licensee may assign the License without the prior consent of Licensor (i) to any Affiliate and (ii) in connection with a Change of Control.
Dispute Resolution³⁷	A senior representative of each party shall first engage in good faith efforts to resolve the dispute, for a period of 30 days from the date that one party notifies the other of its desire to commence Standard Dispute Resolution. If the dispute is not resolved within such time period, the parties shall submit the matter to arbitration under the AAA Commercial Arbitration Rules (with the option to use AAA Expedited Procedures by mutual agreement). The parties must agree to a single arbitrator, and if they cannot agree, one shall be appointed by the President of the City Bar Association of the city in which one of the parties is located (the choice of such city to be determined by a coin toss), provided that sole arbitrator must be experienced in the structuring and negotiation of licenses and commercial agreements in the life sciences industry and be impartial and independent. The arbitration will be conducted over a mutually agreed upon video conferencing platform, unless the parties agree to conduct it live in a mutually agreeable location. Except for the appointment of the arbitrator, which shall follow the timeline set forth in the AAA Road Map (www.adr.org/sites/default/files/document_repository/AAA197_Arbitration_Road_Map.pdf), all the other time periods specified therein shall be cut in half. The parties waive any rights to punitive damages. The parties shall evenly share all costs of such arbitration. This process is referred to as “ Standard Dispute Resolution ”.
Governing Law³⁸	

Defined Terms

“Affiliate”	means any entity which, directly or indirectly, Controls Licensee, is Controlled by Licensee, or is under common Control with Licensee. “ Control ” means having the actual present capacity to elect a majority of the directors, or the power to direct greater than 50% of the voting rights entitled to elect directors of such entity; provided, however, that with respect to any entity in a country where the local law will not permit majority foreign equity participation, control means the ownership or control (directly or indirectly) of the maximum percentage of such outstanding stock or voting rights permitted by local
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³⁷ This is an effort to minimize the friction, time and cost of dispute resolution, without straying too far afield of market norms. Expedited AAA procedures are appropriate where no discovery is necessary; otherwise, that can be perceived as unfair to a party that has an information disadvantage. The standard AAA timelines result in a dispute being resolved no sooner than 258 days post-filing. We deem that unacceptably long, and believe the parties are not jeopardized by shorter timelines. Some university Offices of General Counsel will not agree to arbitration.

³⁸ Certain institutions will be required by statute to use the laws of their state as governing law. Where the parties are not able to agree, they may expressly state: “the parties agree to remain silent with respect to choice of law”.

	law. An entity will be deemed an Affiliate of Licensee solely for the term during which it satisfies the foregoing definition. [VC and its affiliated funds and their respective portfolio companies will not be deemed Affiliates.] ³⁹
“Active Ingredient”	means an active ingredient as defined in 21 CFR 210.3(b)(7).
“Change of Control”	means (i) a consolidation or merger of the Licensee with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, merger or reorganization in which the shares of capital stock of the Licensee immediately prior to such consolidation, merger or reorganization continue to represent a majority of the voting power of the surviving entity immediately after such consolidation, merger or reorganization; (ii) any transaction or series of related transactions to which the Licensee is a party in which in excess of 50% of the Licensee’s voting power is transferred; or (iii) the sale or transfer of all or substantially all of the Licensee’s assets, or the exclusive license of all or substantially all of the Licensee’s material intellectual property; provided that a Change of Control shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the Licensee or any successor, indebtedness of the Licensee is cancelled or converted, or a combination thereof.
“Combination Product”	means a combination of (a) a Licensed Product and (b) Other Components, where such combinations of (a) and (b) 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).
“Commercially Reasonable Efforts”	means, with respect to Licensee’s obligations as to a Licensed Product, the carrying out of such obligations with a level of efforts and resources consistent with those typically expended by a similarly situated company in the applicable industry for the research, development and/or commercialization of a similarly situated therapeutic [or diagnostic product] at a similar stage of development and/or commercialization as such Licensed Product, taking into account the anticipated value of the commercial opportunity, the prevailing regulatory environment (including the likelihood of receiving regulatory approval, and regulatory or data exclusivity), the proprietary position of the Licensed Product, the expected and actual competitiveness of alternative third party products in the marketplace, and other relevant scientific, technical, and commercial factors.
“Cover” or “Covered By”	<i>(For a Patent-only license:)</i> means the manufacture/making, use, marketing, sale, offer to sell, import, export, distribution, rent, end-use license or lease of a product, method or service, which absent the licenses to be granted in accordance with this term sheet, would infringe, or induce or contribute to infringement of, a Valid Claim. <i>(For a Patent and Know-How License):</i> means the manufacture/making, use, marketing, sale, offer to sell, import, export, distribution, rent, end-use license or lease of a product, method or service (a) which absent the licenses to be granted in accordance with this term sheet,

³⁹ Consider whether there are related companies that may meet the definition of Affiliates but should be explicitly excluded (e.g., LLC holding company structures, spin out companies). Conversely, consider whether there are other entities that should be named as Affiliates – e.g., affiliated hospitals in the case of Licensor.

	would infringe, or induce or contribute to infringement of, a Valid Claim; and/or (b) that uses, incorporates, or is discovered, developed or produced through the use of any Licensed Know-How.
“Distributor”	means any person appointed by a Selling Party to distribute, market and sell Licensed Product, with or without packaging rights, in one or more countries in the Territory, in circumstances where such Person purchases its requirements of Licensed Product from the Selling Party, but does not otherwise make any royalty or other payment to the Selling Party in consideration of intellectual property rights with respect to such Licensed Product.
“Effective Date”	means the date of the License Agreement.
“First Commercial Sale”	means the first sale, rental, or lease, in all cases through a bona fide arm’s-length transaction, or commercial use, of any Licensed Product by a Selling Party, excluding the sale of a Licensed Product for use in trials.
“Know-How Product”	means (a) any product, method, or service that is Covered by Licensed Know-How, but excludes Patent Products and (b) which has been nominated as a development candidate within [5] years of the Effective Date. ⁴⁰
“Licensed Compound”	means any molecule or compound that constitutes a Patent Product or Know-How Product that is included within a Combination Product.
“Licensed Know-How”	means any know-how, technical information, tangible materials and/or data, that (a) is expressly identified in <u>Exhibit B</u> or (b) was developed by or under the direction of [Principal Investigator] prior to the Effective Date.
“Licensed Products”	means Patent Products and Know-How Products.
“Licensed Technology”	means Patent Rights and Licensed Know-How.
“Other Components”	means any delivery system(s), devices(s), companion diagnostics and/or one or more additional Active Ingredients.
“Patent Challenge”	means any direct dispute or challenge of the validity, patentability, scope, priority, construction, non-infringement, inventorship, ownership or enforceability of any Patent Right or any claim thereof, or opposition or assistance in the opposition of the grant of any letters patent within the Patent Rights, in any legal or administrative proceedings, including in a court of law, before the USPTO or other agency or tribunal in any jurisdiction, or in arbitration including, without limitation, by reexamination, <i>inter partes</i> review, opposition, interference, post-grant review, nullity proceeding, pre-issuance submission, third party submission, derivation proceeding or declaratory judgment action. The term Patent Challenge will not include (i) Licensee being an essential party in any patent interference proceeding before the

⁴⁰ In some cases, tangible know-how will be licensed, for which it is appropriate to have royalties extend longer, e.g., cell lines. This number should be linked to the diligence milestones, i.e. if there is a diligence milestone to nominate a development candidate within 5 years, the term for this definition should also be 5 years. This time limitation is based on the assumption that most of the value of know-how is transferred during the first five years post-License Agreement.

	USPTO, which interference Licensee acts in good faith to try to settle, or (ii) Licensee, due to its status as an exclusive licensee of patent rights other than the Patent Rights, being named by the licensor of such patent rights as a real party in interest in such an interference, so long as Licensee either abstains from participation in, or acts in good faith to settle, the interference. A Patent Challenge will not include arguments made by Licensee that (a) distinguish the inventions claimed in patents or patent applications owned or controlled by Licensee (“Licensee Patents”) from those claimed in the Patent Rights but (b) do not disparage the Patent Rights or raise any issue of Patent Rights’ compliance with or sufficiency under applicable patent laws, regulations or administrative rules, in each case (x) in the ordinary course of <i>ex parte</i> prosecution of the Licensee Patents or (y) in <i>inter partes</i> proceedings before the USPTO or other agency or tribunal in any jurisdiction (excluding interferences or derivation proceedings), or in arbitration, wherein the Licensee Patents have been challenged.
“Patent Products”	means any product, method, or service that is Covered by a Valid Claim.
“Regulatory Exclusivity”	means any exclusive marketing rights or data exclusivity rights conferred by any regulatory authority with respect to a pharmaceutical product other than Patents, including orphan drug exclusivity, new chemical entity exclusivity data exclusivity, or pediatric exclusivity.
“Selling Party”	means either Licensee or Sublicensee, as the case may be.
“Sublicense”	means any agreement under which Licensee grants any of the rights to Licensed Technology or Licensed Products granted to Licensee under the License Agreement, including, without limitation, any option for such rights.
“Sublicensee”	means any person or entity that is granted a Sublicense.
“Sublicensing Income”	means any cash or equity consideration received by Licensee from a Sublicensee in consideration of the grant of a Sublicense under the Licensed Technology, including any license fee, license maintenance fee, option fee, milestone payments, and annual fees in excess of earned royalties, but excluding (a) royalties paid by a Sublicensee, (b) equity or debt investments in, or loan proceeds to, Licensee, (c) payments by Sublicensees for payment or reimbursement of patent prosecution, defense, enforcement and maintenance and other related expenses, (d) payments by Sublicensees for bona fide research, development, manufacturing or commercialization activities (including, without limitation, payments for FTEs) ⁴¹ , (e) Development Milestone Payments, (f) any profit share for any product, and (g) payment received in a transaction that constitutes a Change of Control of Licensee. Notwithstanding the foregoing, if Licensee receives Sublicensing Income with respect to a Sublicensee’s achievement of any milestone that is substantially similar to a Development Milestone, Sublicensing Income may be reduced by the aggregate amount of such amounts received by Licensee that are due to Licensor for achievement of such Development Milestone.
“Valid Claim”	means, with respect to a particular country, (a) any claim of an issued and unexpired Patent Right in such country that (i) has not been held revoked, unenforceable or invalid by a decision of a court or governmental agency of competent

⁴¹ A Sublicense should clearly delineate what fees are received for R&D activities. Some universities restrict R&D deductions to R&D on the Licensed Products.

	jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal and (ii) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country, or (b) a claim of a pending Patent Right application that has not been finally abandoned or finally rejected or expired and which has been pending [5-7] years from the date of filing of the earliest priority Patent Right application to which such pending Patent Right application is entitled to claim benefit. Any claim in a pending Patent application that is filed after [5-7] years from its earliest priority date will not be considered a Valid Claim until such claim is granted and meets the requirement of subsection (a).
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The parties agree that no binding obligations will be created until the written definitive License Agreement has been duly executed and delivered by authorized representatives of the parties. It is understood that the parties are free to terminate the discussions at any time for any reason prior to the execution of the definitive License Agreement.

EXHIBITS

Exhibit A – Patent Rights

Exhibit B – Licensed Know-How