

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

CASSAVA SCIENCES INC

CIK: [1069530](#) | IRS No.: **911911336** | State of Incorporation: **DE** | Fiscal Year End: **1231**

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SIC: **2834** Pharmaceutical preparations

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): February 27, 2025

Cassava Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-41905

(Commission File Number)

91-1911336

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

**6801 N Capital of Texas Highway, Building 1; Suite 300
Austin, Texas 78731**

(Address of Principal Executive Offices) (Zip Code)

(512) 501-2444

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value	SAVA	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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

Item 1.01 Entry into a Material Definitive Agreement.

On February 26, 2025, Cassava Sciences, Inc. (the “Company”) entered into a License Agreement (the “License Agreement”) with Yale University (“Yale”) pursuant to which the Company was granted exclusive worldwide rights, with rights to sublicense, to Yale’s interest in certain patent and other intellectual property rights that could be useful or necessary to the development and commercialization of simufilam for the treatment of Tuberous Sclerosis Complex (TSC)-related epilepsy and other potential indications. Pursuant to the License Agreement, the Company has agreed to use reasonable commercial efforts to implement a plan that it has designed for such development and commercialization.

In exchange for the rights acquired pursuant to the License Agreement, the Company agreed to pay Yale (i) a nominal upfront license fee, (ii) payments upon the achievement of specified clinical, regulatory and commercial milestones, totaling up to \$4.5 million and (iii) upon transfer to a third party in connection with a regulatory priority review voucher, if issued, a low-to-mid double digit percentage of any consideration received for such transfer. The Company also agreed to pay Yale tiered royalties, ranging from a low- to mid- single digit percentage, on aggregate net sales of licensed products, subject to tiered minimum annual royalty payments ranging from the low- to mid- hundreds of thousands of dollars.

Unless earlier terminated, the License Agreement will continue on a country-by-country basis until the later of (i) the date on which the last valid claim of the license patents expires or otherwise lapses, (ii) the end of any government or regulatory exclusivity period, and (iii) 10 years following the date of first sale of licensed product in such country. The Company may terminate the License Agreement: (i) at its option, upon specified advance notice to Yale and (ii) if Yale commits a material breach of the License Agreement that is not cured within a specified timeframe. Yale may terminate the License Agreement under specified circumstances, including if the Company (i) fails to make any payment due under the License Agreement and fails to cure such non-payment within a specified timeframe, (ii) commits a breach of the License Agreement that is not cured within a specified timeframe, (iii) defaults on a material obligation to any creditor, unless cured within a specified timeframe, (iv) fails to obtain or maintain insurance required by the License Agreement, or (v) brings or assists a patent challenge against Yale (or if a sublicensee does so). In addition, the License Agreement will terminate automatically upon the occurrence of certain bankruptcy and insolvency events involving the Company.

The License Agreement includes customary confidentiality, reporting and inspection, and indemnification provisions.

The foregoing summary of the License Agreement is qualified in its entirety by reference to the text of such agreement, which is filed as Exhibit 10.1 to this report.

Item 7.01. Regulation FD Disclosure.

On February 27, 2025, the Company issued a press release related to the matters described in Item 1.01 of this Current Report on Form 8-K. A copy of the press release is attached as Exhibit 99.1 hereto.

The information furnished in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed to be “filed” for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section, nor shall such information be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
10.1+	License Agreement, dated February 26, 2025, by and between Cassava Sciences, Inc. and Yale University
99.1	Press Release issued by Cassava Sciences, Inc., dated February 27, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Certain portions of this exhibit (indicated by “[***]”) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both not material and is the type of information that the Registrant treats as private or confidential.

SIGNATURE

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

Cassava Sciences, Inc.
a Delaware corporation

Date: February 27, 2025

By: /s/ Eric J. Schoen
Eric J. Schoen
Chief Financial Officer

[*] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.**

THIS LICENSE AGREEMENT (the “AGREEMENT”) by and between YALE UNIVERSITY, a corporation organized and existing under and by virtue of a charter granted by the general assembly of the Colony and State of Connecticut and having a location at 433 Temple Street, New Haven, Connecticut, 06511 (“YALE”), and Cassava Sciences, Inc. NASDAQ: SAVA, a corporation organized and existing under the laws of the State of Delaware, and with principal offices located at 6801 North Capital of Texas Highway, Building 1, Suite 300, Austin, TX 78731 (“LICENSEE”) is effective as of February 26, 2025 (“EFFECTIVE DATE”). YALE and LICENSEE may be referred to herein individually as a “PARTY” and together as the “PARTIES.”

1. BACKGROUND

- 1.1. In the course of research conducted under YALE auspices, Dr. Angelique Bordey in the Department of Neurosurgery and of Cellular And Molecular Physiology at YALE (“BORDEY”) and others under her supervision (the “INVENTORS”), have produced an invention entitled “Targeting filamin A with PTI-125 reduces seizure activity in mTOR-dependent focal epilepsy (FCD and TSC)” (the “INVENTION”).
- 1.2. INVENTORS have assigned or are obligated to assign to YALE all of INVENTORS’ right, title and interest in and to the INVENTION and any resulting patents.
- 1.3. YALE wishes to have the INVENTION and any resulting patents commercialized to benefit the public good.
- 1.4. LICENSEE has represented to YALE to induce YALE to enter into this Agreement that it is experienced in developing products and/or services similar to the LICENSED PRODUCTS and that it shall act diligently to develop and commercialize the LICENSED PRODUCTS in the LICENSED TERRITORY (as defined below).
- 1.5. YALE is willing to grant a license to LICENSEE, subject to the terms and conditions of this AGREEMENT.

In consideration of these statements and mutual promises, YALE and LICENSEE agree to the following terms of this Agreement:

2. DEFINITIONS

The following terms used in this AGREEMENT shall be defined as set forth below:

“AFFILIATE” shall mean any PERSON that directly or indirectly controls, is controlled by or is under common control with LICENSEE. For purposes of this definition, “control” means possession of the power to direct the management of such PERSON, whether through ownership of more than fifty percent (50%) of the voting securities, by contract or otherwise.

“API” shall mean and include PTI-125 as an active pharmaceutical ingredient intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Further, such active pharmaceutical ingredient shall be (a) a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended to be used as a component of a drug and intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the mammalian body; or (b) a substance intended for final crystallization, purification or salt formation, or any combination of those activities, to become the final active pharmaceutical ingredient as defined in clause (a), or as may otherwise be defined by a REGULATORY AUTHORITY.

“BORDEY” is defined in Article 1.1.

“BUSINESS DAY” shall mean any day other than Saturday, Sunday or other day on which commercial banks in the City of New York are authorized or required by law to remain closed.

“CLINICAL TRIAL” shall mean a PHASE 1 CLINICAL TRIAL, a PHASE 2 CLINICAL TRIAL, a PHASE 3 CLINICAL TRIAL or a PIVOTAL CLINICAL TRIAL.

“CONFIDENTIAL INFORMATION” shall mean all information disclosed by one PARTY to the other during the negotiation of or under this Agreement in any manner, whether orally, visually or in tangible form, that relates to LICENSED PATENTS or this AGREEMENT itself, unless such information is subject to an exception described in Article 8.2; provided, however, that CONFIDENTIAL INFORMATION that is disclosed in tangible form shall be marked “Confidential” at the time of disclosure and CONFIDENTIAL INFORMATION that is disclosed orally or visually shall be identified as confidential at the time of disclosure and subsequently reduced to writing, marked confidential and delivered to the other party within [***] of such disclosure. CONFIDENTIAL INFORMATION shall include, without limitation, materials, know-how and data, technical or non-technical, inventions, methods and processes, whether or not patentable. Notwithstanding any other provisions of this definition, CONFIDENTIAL INFORMATION of LICENSEE that is subject to Article 8 of this AGREEMENT is limited to information that LICENSEE supplies pursuant to LICENSEE’s obligations under this AGREEMENT, unless otherwise mutually agreed to in writing by the PARTIES.

“EARNED ROYALTY” is defined in Article 6.1 .

“EFFECTIVE DATE” is defined in the introductory paragraph of this AGREEMENT.

“FDA” shall mean U.S. Food and Drug Administration in the United States. The FDA shall be a REGULATORY AUTHORITY.

“FEDERAL PATENT POLICY” is defined in Article 3.2.

“FIELD” shall mean all uses in humans.

“FIRST SALE” shall mean, for a LICENSED PRODUCT in a country, the first commercial sale in an arms-length transaction of such LICENSED PRODUCT in such country to a THIRD PARTY by or on behalf of LICENSEE, a SUBLICENSEE or an AFFILIATE following receipt of MARKETING APPROVAL in such country for such LICENSED PRODUCT for use with the INDICATION. FIRST SALE will not include: (a) a sale between any of LICENSEE, a SUBLICENSEE or an AFFILIATE; (b) any sale of a LICENSED PRODUCT for the purposes of patient assistance programs, treatment IND sales, named patient sales, compassionate use sales or the like; (c) sales for, or otherwise in support of, CLINICAL TRIALS; or (d) a sale of the LICENSED PRODUCT for a purpose other than for the INDICATION.

“IMPROVEMENTS” is defined in Article 13.7(c).

“INITIATE” and “INITIATION” shall mean the first dosing of a first subject in a CLINICAL TRIAL with a LICENSED PRODUCT by LICENSEE, SUBLICENSEE or an AFFILIATE.

“IND” shall mean an investigational new drug application filed with a REGULATORY AUTHORITY prior to beginning a CLINICAL TRIAL in humans.

“INDICATION” shall mean the prevention or treatment of a disorder covered by a LICENSED PATENT.

“INVENTION” and “INVENTOR” are defined in Article 1.1.

“INVENTOR AGREEMENT” shall mean a consulting or other agreement directly between LICENSEE and an INVENTOR.

“INSOLVENT” shall mean that LICENSEE (i) has ceased to pay its undisputed debts in the ordinary course of business, (ii) is insolvent as defined by the United States Federal Bankruptcy Law, as amended from time to time, or (iii) has commenced bankruptcy, reorganization, receivership or insolvency proceedings, or any other proceeding under any Federal, state or other law for the relief of debtors.

“LICENSE” refers to the license granted under Article 3.1.

“LMF” shall mean the License Maintenance Fee defined in Article 5.2.

“LICENSED INFORMATION” shall mean the devices, concepts, processes, information, data, know-how and the like that are: (i) owned or co-owned by YALE as of the EFFECTIVE DATE, including that discovered in or on behalf of the laboratory of BORDEY; or (ii) necessary or useful for the discovery, development, manufacture, use, sale, offer for sale, import, or other exploitation of LICENSED PRODUCTS, or for the practice or other exploitation of the LICENSED METHODS. LICENSED INFORMATION shall also include the information confidentially provided to LICENSEE under the terms of confidentiality under the [***] MTA. The LICENSED INFORMATION is summarized and incorporated herein as Appendix A2, as listed in Appendix A.

“LICENSED METHOD” shall mean any method, procedure, service or process the practice of which is claimed by a VALID CLAIM of a LICENSED PATENT or which uses a LICENSED PRODUCT.

“LICENSED PATENTS” shall mean the United States or foreign patent application(s) and patents(s) listed in Appendix A1 and owned or co-owned by YALE during the TERM of this AGREEMENT, any and all patent application(s) and patent(s) claiming priority to or sharing priority with any of the foregoing, including any and all continuations, divisionals, and continuations-in-part, reissues, re-examinations, or extensions thereof, or substitutes therefor, and the relevant international equivalents of any of the foregoing. Appendix A1 is incorporated into this AGREEMENT.

“LICENSED PRODUCT” shall mean, in each case, to the extent that LICENSEE does not have a license or other right to exploit, or a patent claiming or describing the API for use in the INDICATION, as of the EFFECTIVE DATE:

- (a) any product (including any apparatus or kit) or component part thereof, if the manufacture, use, sale, offer for sale, import, export or practice thereof is claimed by a VALID CLAIM of a LICENSED PATENT; or
- (b) any LICENSED METHOD; or
- (c) any product that uses, in part or in whole, the LICENSED INFORMATION for its discovery, development, manufacture, use, or sale.

“LICENSED TERRITORY” shall mean worldwide.

“MARKETING APPROVAL” shall mean the receipt by LICENSEE, SUBLICENSEE, or AFFILIATE of an official notification or other comparable communication from a REGULATORY AUTHORITY that allows the commercial marketing (including any pricing or reimbursement approval, should it be required for the marketing) of a LICENSED PRODUCT or LICENSED METHOD directed to the INDICATION.

“MILESTONE EVENT” is defined in Article 5.3.

“MILESTONE PAYMENT” is defined in Article 5.3.

“MRP” shall mean the Minimum Royalty Payments defined in Article 6.5.

“NDA” shall mean either New Drug Application or a Biologics License Application filed with or the equivalent filed with a REGULATORY AUTHORITY to obtain MARKETING APPROVAL for a LICENSED PRODUCT.

“NET SALES” shall mean:

- (a) gross invoice price from the sale or other transfer, practice or disposition of the LICENSED PRODUCTS, or from services performed using or constituting LICENSED PRODUCTS, by LICENSEE, SUBLICENSEES, or AFFILIATES to THIRD PARTIES, except as set forth in (b) of this definition of NET SALES, less the following deductions, provided they actually pertain to the disposition of the LICENSED PRODUCTS and are separately invoiced and reported to YALE :
 - (i) all discounts, credits and allowances on account of returns;
 - (ii) rebates (or their equivalent);

- (iii) transportation and insurance;
- (iv) deductions for Health Care Reform fees and similar deductions to gross invoice price imposed by regulatory or governmental entities;
- (v) duties, taxes and other governmental charges levied on the sale, transportation, importation, exportation, delivery or practice of LICENSED PRODUCTS, but not including income taxes.

No deductions shall be made for any other costs or expenses, including but not limited to commissions to independents, agents or those on LICENSEE's, SUBLICENSEE's or an AFFILIATE's payroll or for the cost of collection, except as set forth above.

- (b) "NET SALES" shall not include the gross invoice price for LICENSED PRODUCTS sold to, or services performed using LICENSED PRODUCTS for, any AFFILIATE or SUBLICENSEE unless such AFFILIATE or SUBLICENSEE is an end-user of any LICENSED PRODUCT, in which case such consideration shall be included in NET SALES at the average selling price charged to a THIRD PARTY during the same quarter, as reduced by applicable deductions.

"[***] MTA" shall mean the Material Transfer Agreement by and between YALE and LICENSEE dated [***] (YALE Ref. #s [***] and [***]).

"PATENT CHALLENGE" shall mean a challenge or opposition to the validity, patentability, enforceability and/or non-infringement of any of the LICENSED PATENTS or otherwise opposing any of the LICENSED PATENTS.

"PERSON" shall mean any individual, firm, corporation, partnership, limited liability company, trust, business trust, joint venture, governmental authority, university, association or other entity.

"PHASE 1 CLINICAL TRIAL" shall mean a human clinical trial constituting the initial introduction of an investigational new drug into humans, as defined in 21 C.F.R §312.21(a) and as practiced according to the standards of the pharmaceutical industry.

"PHASE 2 CLINICAL TRIAL" shall mean a human clinical trial conducted to evaluate the effectiveness of a drug for a particular indication in patients with a disease and to determine the common short-term side effects and risks associated with the drug as defined in 21 C.F.R §312.21(b) and as practiced according to the standards of the pharmaceutical industry.

"PHASE 3 CLINICAL TRIAL" shall mean expanded controlled and uncontrolled human clinical trials performed after PHASE 2 CLINICAL TRIAL(S) evidence suggesting effectiveness of an investigational new drug, as defined by 21 C.F.R §312.21(c), and as practiced according to the standards of the pharmaceutical industry for a PHASE 3 CLINICAL TRIAL and prior to the filing of an NDA or comparable request for MARKETING APPROVAL.

“PIVOTAL TRIAL” shall mean a controlled human clinical trial to evaluate the safety and efficacy of a LICENSED PRODUCT in which data are sufficient to form the basis for the filing of an NDA. A PIVOTAL TRIAL may not necessarily be a PHASE 3 CLINICAL TRIAL.

“PRIORITY REVIEW VOUCHER” shall mean the Priority Review (defined below) voucher issued by the United States Secretary of Health and Human Services to the LICENSEE, SUBLICENSEE or an AFFILIATE as evidenced by publication in the Federal Register (or successor publication) that entitles the holder of such voucher to Priority Review of a single human drug application submitted to the FDA, solely to the extent that the issuance of such Priority Review voucher is attributable to a LICENSED PRODUCT. “Priority Review” means a priority review of and action upon a human drug application by the FDA not later than six (6) months after the filing of such application to the FDA, as defined in and pursuant to the FDA Act (21 U.S.C. 360ff).

“PTI-125” shall mean “simufilam,” or a pharmaceutically acceptable salt and/or solvate thereof, as the API in any LICENSED PRODUCT, the composition of which includes the chemical composition in Figure 1

[***] Figure 1

and that is also known as “PTI-910”, 1-benzyl-8-methyl-1,4,8-triazaspiro(4.5)decan-2-one, and is variously referred to or referenced as among other designations as PubChem 46195331 and 1224591-33-6, Simufilam [USAN], c0105, 6NV440YIO0, C0105M, 1-Benzyl-8-methyl-1,4,8-triazaspiro(4.5)decan-2-one, SIMUFILAM [INN], UNII-6NV440YIO0, 1-benzyl-8-methyl-1,4,8-triazaspiro(4.5)decan-2-one, 1,4,8-Triazaspiro(4.5)decan-2-one, 8-methyl-1-(phenylmethyl)-, C-0105, Simufilam (USAN), WHO 11778, 4-benzyl-8-methyl-1,4,8-triazaspiro[4.5]decan-3-one, PTI-125 dihydrochloride, simufilamum, 4-benzyl-8-methyl-1,4,8-triazaspiro(4.5)decan-3-one, 1,4,8-Triazaspiro[4.5]decan-2-one, 8-methyl-1-(phenylmethyl)-, ChEMBL4650230, SCHEMBL12627054, EX-A5320, AKOS040759870, DA-57876, HY-139142, CS-0179880, D12003, G72535 among other similies and including simufilam dihydrochloride and simufilam dihydrochloride, monohydrate.

“QUALIFIED SUBLICENSEE” shall mean a SUBLICENSEE which is either (i) a biopharmaceutical company with more than \$500 million in revenue in the most recently completed fiscal year, or (ii) a biopharmaceutical company whose products or services primarily use biotechnology or pharmaceutical methods for their production, design or delivery, and whose market capitalization or fair market value exceeds \$500 million at the end of the most recent fiscal year.

“REPORT” is defined in Article 9.1.

“REASONABLE COMMERCIAL EFFORTS” shall mean documented efforts that are consistent with those utilized by companies of similar size and type that have successfully developed products and services similar to the LICENSED PRODUCTS claimed by a VALID CLAIM of the LICENSED PATENTS. In determining REASONABLE COMMERCIAL EFFORTS with respect to a particular LICENSED PRODUCT, LICENSEE may not reduce such efforts due to the competitive, regulatory or other impact of any other product or method that it owns, licenses or is developing or commercializing.

“REGULATORY AUTHORITY” shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the development, manufacture, commercialization of drug or biological products in a country or regulatory jurisdiction, including the FDA in the U.S. and the European Medicines Agency in the European Union. REGULATORY AUTHORITY also includes any non-governmental group licensed by an entity described in the preceding sentence to perform inspections, audits and/or reviews.

“SUBLICENSE” shall mean an agreement between LICENSEE, SUBLICENSEE or an AFFILIATE with a THIRD PARTY conferring any of the rights granted to LICENSEE herein, including but not limited to an option, sublicense, cross-license, revenue-sharing agreement, discovery partnership, co-development partnership, or the grant of any license, privilege, or immunity to make, have made, use, sell, have sold, distribute, practice, import, export or otherwise exploit LICENSED PRODUCTS, or any of the foregoing grants by LICENSEE to a SUBLICENSEE to practice a LICENSED METHOD or to use any LICENSED INFORMATION.

“SUBLICENSEE” shall mean any PERSON with whom a LICENSEE, SUBLICENSEE, or an AFFILIATE has executed a SUBLICENSE.

“SUBLICENSE INCOME” shall mean any consideration in any form received by LICENSEE or an AFFILIATE in connection with a SUBLICENSE. SUBLICENSE INCOME shall include, but not be limited to:

- (a) any consideration in any form, including without limitation, any license signing fee, license maintenance fee, option fee or other payment pursuant to an option, unearned portion of any minimum royalty payment received by LICENSEE equity, distribution or joint marketing fee; and
- (b) research and development funding contractually obligated for work to be performed by LICENSEE after the effective date of a SUBLICENSE in connection with a LICENSED PRODUCT for use in an INDICATION that is in excess of LICENSEE’s cost of performing such future work proportionally committed to such INDICATION; and
- (c) any consideration received for an equity interest in LICENSEE to the extent such consideration exceeds the monetary value of the equity as determined by an independent appraiser mutually agreeable to the PARTIES; and

- (d) any sale or extension of credit to LICENSEE for less than monetary value, as determined by an independent appraiser mutually agreeable to the PARTIES. In the event an extension of credit or loan to LICENSEE by a SUBLICENSEE is forgiven in whole or in part by the SUBLICENSEE, such amount shall constitute SUBLICENSE INCOME;

provided, however, SUBLICENSE INCOME shall not include (i) any EARNED ROYALTY, including the EARNED ROYALTY consideration paid by a SUBLICENSEE to LICENSEE for NET SALES of a LICENSED PRODUCT by such SUBLICENSEE in excess of the EARNED ROYALTY due to YALE for a NET SALE of such LICENSED PRODUCT, (ii) any consideration paid to LICENSEE for rights that are not the subject of this AGREEMENT, or (iii) any consideration received by LICENSEE from enforcement of the LICENSED PATENTS or LICENSED INFORMATION, the distribution of which between the PARTIES being governed by Section 11.2.

“TERM” is defined in Article 3.4.

“THIRD PARTY” shall mean any PERSON that is not YALE, LICENSEE or any of their AFFILIATES.

“UPFRONT FEE” is defined in Article 4.1.

“VALID CLAIM” shall mean a pending, issued or unexpired claim of a LICENSED PATENT so long as such claim shall not have been irrevocably abandoned or declared to be invalid in a non-appealable decision of a court or other authority or competent jurisdiction through no fault or cause of LICENSEE or an AFFILIATE.

3. LICENSE GRANT AND TERM

- 3.1. Subject to all the terms and conditions of this AGREEMENT and upon payment to YALE of the UPFRONT FEE, YALE hereby grants to LICENSEE:

- (a) an exclusive license under the LICENSED PATENTS, to make, have made, use, sell, have sold, offer to sell, import, export, practice, or otherwise exploit the LICENSED PRODUCTS and LICENSED METHODS within the FIELD in the LICENSED TERRITORY and to practice the LICENSED METHODS within the FIELD in the LICENSED TERRITORY;
- (b) a non-exclusive license under the LICENSED INFORMATION to make, have made, use, sell, have sold, offer to sell, import, export, practice, or otherwise exploit the LICENSED PRODUCTS and LICENSED METHODS within the FIELD in the LICENSED TERRITORY; and

- the right to grant SUBLICENSES through multiple tiers to the rights granted under the licenses described in (a) and (b) with prior written notice to YALE if a SUBLICENSE to a QUALIFIED SUBLICENSEE; *provided, however*, any other SUBLICENSEE who is not a QUALIFIED SUBLICENSEE shall require YALE's prior written consent; *provided further, however*, that (i) any SUBLICENSEE who is a vendor providing services or supplying products or components to LICENSEE, a SUBLICENSEE or an AFFILIATE, in each case for a LICENSED PRODUCT, including to contract development, research and manufacturing organizations (each a "CRO"), or (ii) a distributor or other partner engaged by LICENSEE, a SUBLICENSEE or an AFFILIATE to distribute the LICENSED PRODUCTS for the purpose of achieving a NET SALE of such LICENSED PRODUCTS (each a "DISTRIBUTOR"), in each case of (i) and (ii), do not require prior notice or prior consent of YALE if (iii) in either the case of (i) or (ii) in this Section (c), LICENSEE, SUBLICENSEE, or AFFILIATE is granting no other rights from LICENSEE, SUBLICENSEE, or an AFFILIATE, that are granted by YALE to LICENSEE under this AGREEMENT except those that are required by such CRO or DISTRIBUTOR to provide the services described in (i) or make the distributions described in (ii);
- (c) together, (a), (b) and (c) shall be the "LICENSE".
- (d)

The LICENSE granted under this Article 3.1 is subject to the reservation of rights by YALE under Article 3.3.

- To the extent that any invention included within the LICENSED PATENTS has been funded in whole or in part by the United States government, the United States government retains certain rights in such invention as set forth in 35 U.S.C. §§200-212 and all regulations promulgated thereunder, as amended, and any successor statutes and regulations (the "FEDERAL PATENT POLICY"). As a condition of the LICENSE granted hereby, LICENSEE acknowledges and shall comply with all aspects of the FEDERAL PATENT POLICY applicable to the LICENSED PATENTS, including the obligation that LICENSED PRODUCTS used or sold in the United States be manufactured substantially in the United States. Nothing contained in this AGREEMENT obligates or shall obligate YALE to take any action that would conflict in any respect with its past, current or future obligations to the United States Government under the FEDERAL PATENT POLICY with respect to the LICENSED PATENTS.
- 3.2.

- The LICENSE is expressly made subject to YALE's reservation of the right, on behalf of itself and all other non-profit academic and/or non-profit research institutions to make, use and practice the LICENSED PATENTS and LICENSED PRODUCTS solely for non-commercial research, clinical trials, non-commercial teaching purposes, and other non-commercial purposes, and not for purposes of commercial development, use, manufacture, distribution or other exploitation. The foregoing reserved rights will not include a license to any right owned by LICENSEE.
- 3.3.

- Unless terminated earlier as provided in Article 13, the term of this Agreement shall commence on the EFFECTIVE DATE and shall automatically expire on a LICENSED PRODUCT-by-LICENSED PRODUCT and a country-by-country basis, on the later of: (i) the date on which the last of the VALID CLAIMS of the LICENSED PATENTS in such country that claims the use, making, sale, offering for sale, and importing of such LICENSED PRODUCT in such country expires, lapses or is declared to be invalid by a non-appealable decision of a court or other authority of competent jurisdiction through no fault or cause of LICENSEE or an AFFILIATE; or (ii) ten (10) years after the date of FIRST SALE of such LICENSED PRODUCT in such country; or (c) at the end of any governmental or regulatory exclusivity period granted to LICENSEE, SUBLICENSEE, or AFFILIATE for the sale of such LICENSED PRODUCT in such country (the "TERM").
- 3.4.

- Nothing in this AGREEMENT shall be construed to grant by implication, estoppel or otherwise any licenses under patents of YALE other than the LICENSED PATENTS. Except as expressly provided in this AGREEMENT, under no circumstances will LICENSEE, as a result of this AGREEMENT, obtain any interest in or any other right to any technology, know-how, patents, patent applications, materials or other intellectual or proprietary property of YALE. Except as expressly provided in this AGREEMENT, under no circumstances will YALE, as a result of this AGREEMENT, obtain any interest in or any other right to any technology, know-how, patents, patent applications, materials or other intellectual or proprietary property of LICENSEE.
- 3.5.

4. DUE DILIGENCE

- LICENSEE has designed a plan for developing and commercializing the LICENSED PATENTS that includes a proposed budget and reasonable description of research and development, testing, government approval, manufacturing, marketing and sale or lease of LICENSED PRODUCTS ("PLAN") that represents REASONABLE COMMERCIAL EFFORTS to develop and commercialize LICENSED PRODUCTS and that is attached to this AGREEMENT as Appendix B and incorporated herein by reference. YALE has approved the PLAN.
- 4.1.

- LICENSEE shall use REASONABLE COMMERCIAL EFFORTS, within [***] after the EFFECTIVE DATE of this Agreement, to begin to implement the PLAN at its sole expense and thereafter to implement the PLAN and to develop and commercialize LICENSED PRODUCTS and develop markets for the LICENSED PRODUCTS.
- 4.2.

- [***] after the EFFECTIVE DATE of this Agreement and on each anniversary of the EFFECTIVE DATE thereafter, LICENSEE shall provide YALE with the REPORT and an updated and revised copy of the PLAN which shall indicate LICENSEE's progress and problems to date in development and commercialization of LICENSED PRODUCTS and a forecast and schedule of major events required to develop and market the LICENSED PRODUCTS. Such updated PLAN shall clearly indicate which of LICENSEE's products or services are LICENSED PRODUCTS, which LICENSED PATENTS claim each such LICENSED PRODUCT.
- 4.3.

- (a) Within [***] prior to assignment by LICENSEE pursuant to Article 18.7, the assignee shall provide YALE with an updated and revised copy of the PLAN.

- (b) Provided each such updated and revised PLAN is consistent with the activities required under Section 4.5 of this Section, then such updated and revised PLAN shall be deemed substituted into this Agreement as Appendix B. YALE shall provide LICENSEE notice as to whether such PLAN is considered by YALE to be consistent with Section 4.5 within [***] of receipt pursuant to Section 15 herein.

4.4. LICENSEE shall immediately send YALE a notice of abandonment if at any time LICENSEE (a) abandons or suspends its research, development or marketing of the LICENSED PRODUCTS, or its intent to research, develop and market LICENSED PRODUCTS, or (b) fails to comply with its obligations under this Article for a period exceeding [***].

4.5. In addition to LICENSEE's other obligations herein, LICENSEE agrees that YALE shall be entitled to terminate this AGREEMENT pursuant to Article 13.1(b) for material breach of this Agreement if LICENSEE has by failing to:

- (a) with respect to Financial Diligence, incur direct expenses, which may include reasonable cost of services-in-kind contracted to a THIRD PARTY, and reported to YALE in a REPORT ("[***] Spend") towards research, development, or marketing of LICENSED PRODUCTS according to the following schedule:

Date	[***] Spend*
First Anniversary of the EFFECTIVE DATE	[***]
Second Anniversary of the EFFECTIVE DATE	[***]
Third Anniversary of the EFFECTIVE DATE and every Anniversary thereafter	[***]

**provided, however, if LICENSEE, SUBLICENSEE, or an AFFILIATE is in compliance with the Product Development Diligence in (b) below, then such Annual Spend obligations shall not apply.*

(b) with respect to Product Development Diligence to:

- i. have a pre-IND meeting with the FDA or other REGULATORY AUTHORITY within [***] of the EFFECTIVE DATE for a first LICENSED PRODUCT, subject to an extension of [***] upon written request and demonstration of REASONABLE COMMERCIAL EFFORT and compliance with (a) above by LICENSEE;

or

- ii. LICENSEE, its SUBLICENSEES or AFFILIATES has failed to file an IND and INITIATE a CLINICAL TRIAL for a first LICENSED PRODUCT within [***] of the EFFECTIVE DATE, subject to an extension of up to [***] upon written request by LICENSEE, demonstration of REASONABLE COMMERCIAL EFFORTS, compliance with (i) above, and by LICENSEE provision to YALE of the minutes of the Pre-IND meeting with the FDA for such LICENSED PRODUCT; or

- iii. Following the filing of an IND for a first LICENSED PRODUCT, LICENSEE, its SUBLICENSEES or AFFILIATES has failed to demonstrate ongoing pre-clinical or clinical development of LICENSED PRODUCTS, which shall be evidenced by a written report documenting LICENSEE's accomplishment at least one (1) of the following activities in this Article 4.5(b)(iii) in any given [***] period starting from the date of the IND filing:

1. having manufactured LICENSED PRODUCT suitable for CLINICAL TRIALS of a LICENSED PRODUCT and in support for an approved IND;
2. having engaged in study preparation, including the manufacture of LICENSED PRODUCT, implementation, performance, results analysis or reporting of a Phase 1, 2, or 3 CLINICAL TRIAL with respect to a LICENSED PRODUCT, including the preparation of regulatory documents for filing with a REGULATORY AUTHORITY;
3. having responded to regulatory requests/issues relating to a Phase 1, 2, or 3 CLINICAL TRIAL of a LICENSED PRODUCT;
4. having prepared documents for an NDA filing to seek MARKETING APPROVAL of a LICENSED PRODUCT in the United States or Europe;
5. having filed an NDA for MARKETING APPROVAL in the United States or Europe for a LICENSED PRODUCT; or
6. following MARKETING APPROVAL of a LICENSED PRODUCT or LICENSED METHOD, having made a FIRST SALE of a LICENSED PRODUCT in the United States or Europe;

Notwithstanding the foregoing in this Article 4, if LICENSEE has not employed REASONABLE COMMERCIAL EFFORTS in developing and selling LICENSED PRODUCTS within at least the United States, then YALE may, at its sole discretion, terminate the LICENSE pursuant to Article 13 in the United States.

- 4.6. LICENSEE agrees that LICENSED PRODUCTS will be offered for sale in low-income and lower-middle income countries at a price that is no more than [***].

5. LICENSE ISSUE PAYMENT; LICENSE MAINTENANCE FEES; MILESTONE PAYMENTS

- 5.1. LICENSEE shall pay to YALE within [***] after the EFFECTIVE DATE a non-refundable license issue payment of [***] (“UPFRONT FEE”), together with a payment of [***] which is intended to reflect the unreimbursed patent expenses incurred by YALE prior to the EFFECTIVE DATE for prosecution of the LICENSED PATENTS.

- 5.2. During the TERM of this AGREEMENT, LICENSEE agrees to pay to YALE an annual License Maintenance Fee (“LMF”) commencing on the [***] of the EFFECTIVE DATE and on every anniversary thereafter, until LICENSEE starts to pay MRP under Article 6.5 according to the following schedule:

Anniversaries of the EFFECTIVE DATE	LMF
Anniversaries [***] & [***]	[***]
Anniversary [***]	[***]
Anniversary [***] and each anniversary thereafter	[***]

- 5.3. LICENSEE shall pay a MILESTONE PAYMENT to YALE for each LICENSED PRODUCT developed by LICENSEE, SUBLICENSEE of AFFILIATES that achieves a MILESTONE EVENT, as described below:

“MILESTONE EVENT”	“MILESTONE PAYMENT”
Upon INITIATION of at the first PHASE 2 CLINICAL TRIAL for the first LICENSED PRODUCT	[***]
Upon INITIATION of a PHASE 3 CLINICAL TRIAL for the first LICENSED PRODUCT	[***]
Upon receiving the first MARKETING APPROVAL in the United States for the first LICENSED PRODUCT	[***]
Upon the first anniversary of the FIRST SALE in the United States of a LICENSED PRODUCT	[***]
Upon use of a PRIORITY REVIEW VOUCHER for a LICENSED PRODUCT	[***]
Upon use of a PRIORITY REVIEW VOUCHER for a product of LICENSEE or an AFFILIATE that is not a LICENSED PRODUCT.	[***]
Notwithstanding the provisions for consideration amounts due to YALE for SUBLICENSE INCOME, upon transfer of a PRIORITY REVIEW VOUCHER to a THIRD PARTY, including a SUBLICENSEE	[***]

In the event a LICENSED PRODUCT bypasses a given CLINICAL TRIAL, then the MILESTONE PAYMENT due to YALE upon INITIATION of the subsequent CLINICAL TRIAL shall be the sum of the MILESTONE PAYMENTS for the preceding CLINICAL TRIAL(S) and the subsequent CLINICAL TRIAL.

A MILESTONE PAYMENT shall be made only one (1) time for a given LICENSED PRODUCT upon achievement of the corresponding MILESTONE EVENT.

- 5.4. Neither the license issue payment set forth in Article 5.1 nor the LMF of Article 5.2 nor the MILESTONE PAYMENTS set forth in Article 5.3 shall be credited against EARNED ROYALTIES payable under Article 6, or any other payment due to YALE, including SUBLICENSE INCOME.

6. EARNED ROYALTIES; MINIMUM ROYALTY PAYMENTS

- 6.1. During the TERM of this AGREEMENT, as partial consideration for the LICENSE:

- (a) LICENSEE shall pay to YALE a royalty on worldwide cumulative NET SALES of LICENSED PRODUCTS by LICENSEE or its SUBLICENSEES or AFFILIATES ("EARNED ROYALTY") according to the following schedule:

Cumulative annual NET SALES of a LICENSED PRODUCT sold	EARNED ROYALTY in a country in the LICENSED TERRITORY with a VALID CLAIM	EARNED ROYALTY in a country in the LICENSED TERRITORY without a VALID CLAIM for the use of LICENSED INFORMATION
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Notwithstanding anything to the contrary in this Section 6.1(a), if LICENSEE, SUBLICENSEE, or an AFFILIATE cannot document that a sale of a product containing API was not a NET SALE of LICENSED PRODUCT, then the consideration received for such sale of a product containing API will be added to the sales or other disposition of LICENSED PRODUCT in the calculation of NET SALES for the purposes of determining the EARNED ROYALTY due to YALE.

- (b) In the event that LICENSEE is legally required to pay running royalties to an unaffiliated THIRD PARTY for a license to a THIRD PARTY issued patent that the LICENSED PRODUCTS and their exploitation would otherwise infringe, then the EARNED ROYALTY owed to YALE on NET SALES of the same LICENSED PRODUCT under Article 6.1 may be reduced by up to [***] of the royalty amount due to such THIRD PARTY during the applicable royalty period for the same LICENSED PRODUCT in the corresponding territory of such THIRD PARTY issued patent; *provided, however*, that in no event shall the EARNED ROYALTY payable to YALE on any LICENSED PRODUCT be reduced below [***] of the EARNED ROYALTY otherwise due to YALE in a particular royalty period for a particular territory of such THIRD PARTY issued patent, and provided, further that any royalties due to any THIRD PARTY that are not offset against the EARNED ROYALTY due to YALE in the applicable royalty period shall not be carried forward for offset in a subsequent period.
- (c) Notwithstanding anything to the contrary in this AGREEMENT, except as specifically set forth in this AGREEMENT, there shall not be any further deductions in the calculation of the EARNED ROYALTY payable to YALE.
- (d) Any reduction in the EARNED ROYALTY due to YALE as a consequence of a deduction permitted under Article 6.1 of this AGREEMENT shall require that LICENSEE report, on a LICENSED PRODUCT-by-LICENSED PRODUCT and territory-by-territory basis, the nature and the amount of such deduction taken in any given payment period for an EARNED ROYALTY, pursuant to the reporting provisions of this AGREEMENT.

6.2. In the event that (i) LICENSEE or any of its AFFILIATES brings a PATENT CHALLENGE anywhere in the world, (ii) LICENSEE or any of its AFFILIATES assists another party in bringing a PATENT CHALLENGE anywhere in the world (except as required under a court order or subpoena), or (iii) a SUBLICENSEE brings a PATENT CHALLENGE anywhere in the world and LICENSEE does not use COMMERCIALY REASONABLE EFFORTS (other than the payment of funds to such SUBLICENSEE) to cause the SUBLICENSEE to cease the PATENT CHALLENGE, then the following provisions shall apply:

- (a) All payments other than patent expenses and the MILESTONE PAYMENT for transfer of a PRIORITY REVIEW VOUCHER due to YALE under this AGREEMENT shall be tripled during the pendency of the PATENT CHALLENGE and shall remain payable to YALE when due.
- (b) if the PATENT CHALLENGE is inconclusive or results in a determination that at least one challenged claim is both valid and infringed by the use, making, selling, offer for sale, or importing of a LICENSED PRODUCT,
 - (1) all payments other than the patent expenses and the MILESTONE STONE PAYMENT for transfer of a PRIORITY REVIEW VOUCHER due to YALE under this AGREEMENT shall be tripled for the remainder of the TERM.
 - (2) LICENSEE shall promptly reimburse YALE for all legal fees and expenses incurred in YALE's defense against the PATENT CHALLENGE.
- (c) In the event that such a PATENT CHALLENGE is successful, LICENSEE will have no right to recoup any payments made prior to the final, non-appealable determination of a court of competent jurisdiction.

6.3. Neither LICENSEE nor any of its AFFILIATES shall, and LICENSEE shall use COMMERCIALY REASONABLE EFFORTS to cause SUBLICENSEES to not, bring a PATENT CHALLENGE without first providing YALE [***] written notice setting forth (a) precisely which claims and patents are being challenged or claimed not to be infringed by a LICENSED PRODUCT, (b) a clear statement of the factual and legal basis for the challenge, and (c) an identification of all prior art and other matter believed to invalidate any claim of the LICENSED PATENT or which supports the claim that the LICENSED PATENT is not infringed by a LICENSED PRODUCT.

6.4. LICENSEE shall pay all EARNED ROYALTIES accruing to YALE within [***] from the end of each calendar quarter (March 31, June 30, September 30 and December 31), beginning in the [***] calendar quarter in which NET SALES occur. Unless YALE requests otherwise, LICENSEE shall report all EARNED ROYALTIES and other payments accruing to YALE on a quarterly basis, but shall defer payments accruing to YALE that do not, in total, exceed [***] in any given quarter until the earlier of (1) the end of the calendar year, or (2) the quarter upon which the cumulative accrued royalties and other payments exceed [***].

During the TERM of this AGREEMENT, LICENSEE agrees to pay YALE annual Minimum Royalty Payments (“MRP”).

- 6.5. The first MRP shall be due on the [***] of EFFECTIVE DATE to occur after the FIRST SALE of a first LICENSED PRODUCT according to the following schedule:

Anniversaries of EFFECTIVE DATE following FIRST SALE of a first LICENSED PRODUCT	MRP
Anniversary [***]	[***]
Anniversary [***]	[***]
Anniversary [***]	[***]
Anniversary [***] and each Anniversary thereafter during the TERM	[***]

The MRP shall be paid quarterly. The MRP shall be creditable against any EARNED ROYALTY payments actually paid to YALE in the following [***] from such MRP quarterly payment.

- 6.6. LICENSEE shall continue to pay the MRP until the end of the TERM. YALE shall fully credit each MRP made against any EARNED ROYALTIES payable by LICENSEE in the same calendar year.

All EARNED ROYALTIES and other payments due under this AGREEMENT shall be paid to YALE in United States Dollars after receipt of the applicable invoice from YALE. With the exception of invoices for patent costs, LICENSEE shall

- 6.7. request an invoice from YALE for such payments within [***] of an invoiceable event under this AGREEMENT. In the event that conversion from foreign currency is required in calculating a payment under this AGREEMENT, the exchange rate used shall be the Interbank rate quoted by [***] at the time the payment is due.

- (a) If an EARNED ROYALTY, MRP, or any other payment due under this Agreement is overdue, including for failure to notify YALE by request for an invoice for such payment, LICENSEE shall be charged a [***] surcharge on the amount due plus interest at the rate of [***] per month or fraction thereof. Failure of LICENSEE to pay the amounts due shall be grounds for termination by YALE pursuant to Article 13. The payment of such interest shall not foreclose YALE from exercising any other right it may have as a consequence of the failure of LICENSEE to make any payment when due.
- (b) YALE shall be entitled to recover reasonable attorneys’ fees and costs related to the administration or enforcement of this Agreement for the collection of EARNED ROYALTIES, patent expenses, or other payments due under this AGREEMENT, following such failure to pay.

7. SUBLICENSES

7.1. Except as set forth in Article 3.1(c), LICENSEE shall not SUBLICENSE the rights granted to it under this Agreement without the prior written consent of YALE. In the event YALE consents to a SUBLICENSE under this Article 7.1, in addition to any other terms and conditions YALE may require, the provisions of Articles 7.2, 7.3 and 7.4 shall apply.

7.2. Any SUBLICENSE granted by LICENSEE shall include all definitions and provisions of this AGREEMENT that are applicable to such SUBLICENSE in substantially the same form as set forth herein, and such other provisions as are needed to enable LICENSEE to provide YALE the protections and benefits contemplated herein. LICENSEE will provide YALE with a copy of each unredacted such SUBLICENSE agreement (and all amendments thereof) promptly after execution. LICENSEE shall include the following provisions in all SUBLICENSES, other than to CROs or DISTRIBUTORS who do not otherwise qualify as a SUBLICENSEE under this AGREEMENT:

- (a) In the event that SUBLICENSEE brings a PATENT CHALLENGE anywhere in the world or assists another party in bringing a PATENT CHALLENGE anywhere in the world (except as required under a court order or subpoena) then the payments due under such SUBLICENSE will be tripled or the SUBLICENSE shall be terminated by LICENSEE; and
- (b) LICENSEE agrees that it has sole responsibility to promptly provide YALE
 - i. with a copy of each unredacted SUBLICENSE agreement (or amendment thereof) promptly, but no later than [***], after execution and to equally promptly notify YALE of termination of any such SUBLICENSE; and
 - ii. forward or summarize and deliver unredacted copies of all reports provided to LICENSEE or and AFFILIATE by SUBLICENSEES to the extent they include a LICENSED PRODUCT and relate to the INDICATION promptly, but no later than [***], after receipt by LICENSEE or an AFFILIATE.

- (c) In the event of termination of this AGREEMENT, YALE may elect to convert the SUBLICENSE to SUBLICENSEE into a direct license with YALE and the SUBLICENSEE, and upon such election the SUBLICENSE shall become a two-party agreement between YALE and the SUBLICENSEE, and SUBLICENSEE shall render to YALE all payments that the SUBLICENSEE would have otherwise owed to LICENSEE under the SUBLICENSE. In such instance, YALE shall not be required to assume any additional obligations or responsibilities beyond those contained in this AGREEMENT.

LICENSEE shall remain responsible for the performance of all SUBLICENSEES under any such SUBLICENSE as if such performance were carried out by LICENSEE itself, including, without limitation, the payment of any royalties or other payments provided for hereunder, regardless of whether the terms of any SUBLICENSE provide for such amounts to be paid by the SUBLICENSEE directly to YALE. A breach of this provision shall constitute a material breach that is subject to Article 13.1(b).

7.3. Sales by SUBLICENSEES of LICENSED PRODUCTS will apply to NET SALES in accordance with the definition of NET SALES. LICENSEE shall pay EARNED ROYALTIES to YALE on sales by SUBLICENSEE at the same rate as if such NET SALES had been made directly by LICENSEE under Section 6.

7.4. LICENSEE shall pay to YALE a portion of any SUBLICENSE INCOME according to the following schedule:

Stage of development of a given LICENSED PRODUCT when a given SUBLICENSE is executed	Percent of SUBLICENSE INCOME due to YALE
Prior to INITIATION of a first PHASE 2 CLINICAL TRIAL of a LICENSED PRODUCT or LICENSED METHOD.	***
After INITIATION of a first PHASE 2 CLINICAL TRIAL but prior to filing for MARKETING APPROVAL of a LICENSED PRODUCT or LICENSED METHOD.	***
After filing for MARKETING APPROVAL for LICENSED PRODUCT or LICENSED METHOD.	***

8. CONFIDENTIALITY AND PUBLICITY

- 8.1. Subject to the parties' rights and obligations pursuant to this Agreement, YALE and LICENSEE agree that during the TERM of this Agreement and for *** thereafter, each of them:
- (a) will keep confidential and will cause their AFFILIATES and, in the case of LICENSEE, its SUBLICENSEES, to keep confidential, CONFIDENTIAL INFORMATION disclosed to it by the other PARTY, by taking whatever action the PARTY receiving the CONFIDENTIAL INFORMATION would take to preserve the confidentiality of its own CONFIDENTIAL INFORMATION, which in no event shall be less than reasonable care; and;
 - (b) will only disclose that part of the other's CONFIDENTIAL INFORMATION to its officers, employees or agents, under requirements of confidentiality, for purposes of carrying out its rights and responsibilities under this AGREEMENT; and

- (c) will not use the other PARTY's CONFIDENTIAL INFORMATION other than as expressly permitted by this AGREEMENT or disclose the other PARTY's CONFIDENTIAL INFORMATION to any THIRD PARTIES (other than to agents under requirements of confidentiality) under any circumstance without advance written permission from the other PARTY; and
- (d) will, within [***] of termination of this AGREEMENT, return all the CONFIDENTIAL INFORMATION disclosed to it by the other PARTY pursuant to this AGREEMENT except for one copy which may be retained by the recipient for monitoring compliance with this Article 8 and any surviving clauses.

8.2. The obligations of confidentiality described above shall not pertain to that part of the CONFIDENTIAL INFORMATION that:

- (a) is shown to have been known to or developed by the recipient prior to the disclosure by the disclosing PARTY; or
- (b) is at the time of disclosure or has become thereafter publicly known through no fault or omission attributable to the recipient; or
- (c) is rightfully given to the recipient from sources independent of the disclosing PARTY; or
- (d) is independently developed by the receiving party without use of or reference to the CONFIDENTIAL INFORMATION of the other PARTY; or
- (e) is required to be disclosed by law in the opinion of recipient's attorney, but only after the disclosing PARTY is given prompt written notice and an opportunity to seek a protective order.

8.3. The financial terms of this AGREEMENT constitute CONFIDENTIAL INFORMATION of each PARTY.

9. REPORTS, RECORDS AND INSPECTIONS

9.1. LICENSEE shall, within [***] after the calendar year in which NET SALES first occur, and within [***] after each calendar quarter (March 31, June 30, September 30 and December 31) thereafter, provide YALE with a written report ("REPORT") detailing the NET SALES and uses, if any, made by LICENSEE, its SUBLICENSEES and AFFILIATES of LICENSED PRODUCTS during the preceding calendar quarter and calculating the payments due pursuant to Article 6. NET SALES of LICENSED PRODUCTS shall be deemed to have occurred on the date of invoice for such LICENSED PRODUCTS. The REPORT shall be in the form attached as Exhibit 9.1, or in such other form as is reasonably acceptable to the PARTIES and containing the information requested in Exhibit 9.1. Each such report shall be signed by an officer of LICENSEE (or the officer's designee), and must include:

- (a) the number or amount, as appropriate, of LICENSED PRODUCTS manufactured, sold, practiced, leased or otherwise transferred or disposed of by LICENSEE, SUBLICENSEES and AFFILIATES;

- (b) a calculation of NET SALES for the applicable reporting period in each country, including the gross invoice prices charged for the LICENSED PRODUCTS and any permitted deductions made pursuant to the definition of NET SALES;
- (c) a calculation of total royalties or other payment due, including any exchange rates used for conversion;
- (d) names and addresses of all SUBLICENSEES, other than CROs and DISTRIBUTORS, and the type and amount of any SUBLICENSE INCOME received from each such SUBLICENSEE; and
- (e) identification of any INVENTOR AGREEMENT(S) in effect during the previous calendar quarter .

9.2. LICENSEE, AFFILIATES and its SUBLICENSEES shall keep and maintain complete and accurate records and books containing an accurate accounting of all data in sufficient detail to enable verification of EARNED ROYALTIES and other payments under this Agreement. LICENSEE shall preserve such books and records for [***] after the calendar year to which they pertain. Such books and records shall be open to inspection by YALE or an independent certified public accountant selected by YALE, at YALE's expense, during normal business hours upon [***] prior written notice, for the purpose of verifying the accuracy of the reports and computations rendered by LICENSEE. In the event LICENSEE underpaid the amounts due to YALE with respect to the audited period by more than [***], LICENSEE shall pay the reasonable cost of such examination, together with the deficiency not previously paid and interest from the due date of such payment, calculated at the rate set forth in Article 6.7, within [***] of receiving notice thereof from YALE.

9.3. In the event LICENSEE is not or is no longer a publicly-traded company or is otherwise not obliged by law or regulation to make public disclosures of financial information, then on or before the [***] following the close of LICENSEE's fiscal year, LICENSEE shall provide YALE with LICENSEE's financial statements for the preceding fiscal year including, at a minimum, a balance sheet and an income statement. Such report of financial information shall be signed by an officer of LICENSEE.

10. PATENT PROTECTION

10.1. LICENSEE shall be responsible for all past, present and future costs of filing, prosecution and maintenance of all United States patent applications and patents contained in the LICENSED PATENTS. Any and all such United States patent applications, and resulting issued patents, shall remain the property of YALE.

10.2. LICENSEE shall be responsible for all past, present and future costs of filing, prosecution and maintenance of all foreign patent applications and patents contained in the LICENSED PATENTS in the countries outside the United States in the LICENSED TERRITORY selected by YALE and agreed to in writing by LICENSEE. All such applications or patents shall remain the property of YALE. LICENSEE acknowledges that YALE shall not be required to file any such applications in low or lower-middle income countries, as designated by the World Bank (www.worldbank.org). Furthermore, LICENSEE agrees not to file any patent rights that are owned by LICENSEE and that claim LICENSED PRODUCTS (excluding any rights LICENSEE owns or controls as of the EFFECTIVE DATE that cover the making or use of PTI-125, provided that such excluded patents or rights are not LICENSED PATENTS) in any such low-income or lower-middle income countries.

10.3. If, upon invoice by YALE, LICENSEE does not pay the expenses of filing, prosecuting or maintaining a LICENSED PATENT in a country in the LICENSED TERRITORY, then LICENSEE's rights under this Agreement with respect to such LICENSED PATENT in such country shall terminate upon written notice from YALE. YALE reserves the right to require LICENSEE to pay patent expenses in advance of instructions being given by YALE to counsel, based upon good-faith estimates from YALE's patent counsel provided to LICENSEE.

10.4. The costs mentioned in Articles 10.2 and 10.3 shall include, but are not limited to, any past, present and future taxes, annuities, working fees, maintenance fees, renewal and extension charges. Payment of such costs shall be made, at YALE's sole discretion by reimbursement to YALE, or in advance to YALE based on good faith estimates from YALE's patent counsel. In either case, LICENSEE shall make payment directly to the appropriate party within [***] of receiving its invoice. If LICENSEE fails to make payment to YALE or patent counsel, as appropriate, within the thirty-day period, LICENSEE shall be charged a [***] surcharge on the invoiced amount plus interest at the rate of [***] per month or fraction thereof or such higher amount as may be charged by patent counsel. The payment of such interest shall not foreclose YALE from exercising any other right it may have as a consequence of the failure of LICENSEE to make any payment whatsoever when due. YALE shall be entitled to recover reasonable attorneys' fees and costs incurred in securing such payment.

10.5. All patent applications under the LICENSED PATENTS shall be prepared, prosecuted, filed and maintained by independent patent counsel chosen by YALE. Said independent patent counsel shall be ultimately responsible to YALE. YALE shall instruct patent counsel to keep both YALE and LICENSEE fully informed of the progress of all patent applications and patents, and to give both YALE and LICENSEE reasonable opportunity to comment on the type and scope of useful claims and the nature of supporting disclosures. YALE will not finally abandon any patent application for which LICENSEE is bearing expenses without LICENSEE's consent. YALE shall have no liability to LICENSEE for damages, whether direct, indirect or incidental, consequential or otherwise, allegedly arising from its good faith decisions, actions and omissions in connection with such prosecution.

- 10.6. Subject to any limitation under applicable law, LICENSEE shall mark, and shall require AFFILIATES and SUBLICENSEES to mark, all LICENSED PRODUCTS, that are tangible products, with the numbers of all patents included in LICENSED PATENTS with a VALID CLAIM that cover the LICENSED PRODUCTS. Without limiting the foregoing, all LICENSED PRODUCTS shall be marked in such a manner as to conform with the patent marking notices required by the law of any country where such LICENSED PRODUCTS are made, sold, used or shipped, including, but not limited to, the applicable patent laws of that country.

11. INFRINGEMENT AND LITIGATION

- 11.1. Each PARTY shall promptly notify the other in writing in the event that it obtains knowledge of infringing activity by THIRD PARTIES, or is sued or threatened with an infringement suit, in any country in the LICENSED TERRITORY as a result of activities that concern the LICENSED PATENTS, and shall supply the other PARTY with documentation of the alleged infringing activities that it possesses.

- 11.2. During the TERM of this AGREEMENT:

- (a) LICENSEE shall have the first right, but not the obligation to enforce the LICENSED PATENTS against infringement or interference and defend the LICENSED PATENTS against any challenge to validity and enforceability in the FIELD and in the LICENSED TERRITORY by THIRD PARTIES. This right includes bringing any legal action for infringement and defending any counter claim of invalidity or enforceability or action of a THIRD PARTY for declaratory judgment for non-infringement or non-interference. If, in the reasonable opinion of both LICENSEE's and YALE's respective counsel, YALE is required to be a named party to any such suit for standing purposes, LICENSEE may join YALE as a party; provided, however, that (i) YALE shall not be the first named party in any such action, (ii) the pleadings and any public statements about the action shall state that the action is being pursued by LICENSEE and that LICENSEE has joined YALE as a party; and (iii) LICENSEE shall keep YALE reasonably apprised of all developments in any such action. LICENSEE may settle such suits solely in its own name and solely at its own expense and through counsel of its own selection; provided, however, that no settlement shall be entered without YALE's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed; provided, that YALE may withhold such consent if such settlement would in any manner constitute or incorporate an admission by YALE or, require YALE to take or refrain from taking any action. In no event shall such settlement be entered into without first notifying and disclosing such settlement to YALE prior to such settlement being entered into. LICENSEE shall bear the expense of such legal actions, including the reasonable cost of counsel for joining YALE as a party if LICENSEE has joined YALE as a party. Except for providing reasonable assistance, at the request and expense of LICENSEE, YALE shall have no obligation regarding the legal actions described in this Article 11.2(a) unless required to participate by law. However, YALE shall have the right to participate in any such action through its own counsel and at its own expense. Any recovery shall first be applied to LICENSEE's out of pocket expenses and second shall be applied to YALE's out of pocket expenses, including legal fees. LICENSEE shall recover [***] and YALE shall recover [***] of any excess recovery over those expenses.

In the event LICENSEE fails to initiate and pursue or participate in the actions described in Article 11.2(a) in a given jurisdiction within [***] of (a) notification of infringement from YALE or (b) the date LICENSEE otherwise first becomes aware of an infringement, whichever is earlier, YALE may, in its sole discretion, convert the LICENSE granted in Article 3 for such jurisdiction to a nonexclusive license, and issue licenses to third parties under the LICENSED PATENTS in such jurisdiction to make, have made, use, sell, have sold, import, export, or practice LICENSED PRODUCTS within the FIELD in such jurisdiction within the LICENSED TERRITORY. Additionally, YALE shall have the right to initiate legal action such as that described in Article 11.2(a) in such jurisdiction at its own expense. In such case, LICENSEE shall provide reasonable assistance to YALE if requested to do so, including joining as a party to such action if required for legal standing, in each case at YALE's cost and expense. YALE may settle such actions solely in its own name and through its own counsel; provided, however, that if LICENSEE is joined, no settlement shall be entered without LICENSEE's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed, if such settlement would in any manner constitute or incorporate an admission by LICENSEE, require LICENSEE to take or refrain from taking any action or diminish any of LICENSEE's then existing rights. Any recovery shall first be applied to YALE's out of pocket expenses and second shall be applied to LICENSEE's reasonable out of pocket expenses, if joined, including legal fees. YALE can retain any remaining recoveries.

(b)

In the event LICENSEE is permanently enjoined from exercising its LICENSE under this Agreement or selling LICENSED PRODUCT or PTI-125 for the INDICATION pursuant to an infringement action brought by a third party, or if both LICENSEE and YALE elect not to undertake the defense or settlement of a suit alleging infringement for a period of [***] from notice of such suit, in each case in a given jurisdiction, then either PARTY shall have the right to terminate this Agreement in such jurisdiction following [***] written notice to the other PARTY in accordance with the terms of Article 15.

(c)

Notwithstanding the foregoing, neither LICENSEE nor YALE shall take any action to enforce the LICENSED PATENTS, or patent rights owned by LICENSEE and which claim the LICENSED PRODUCTS, in low or lower-middle income countries, where such action is intended to prevent the sale of LICENSED PRODUCTS in any such countries. However, LICENSEE and/or YALE may take such action in any such country, provided that such action is intended to prevent the manufacturing of LICENSED PRODUCTS for export to countries that are not low-income or lower-middle countries.

(d)

Recording of Agreement. If LICENSEE is required for any reason to register or record this AGREEMENT with any patent office in any jurisdiction, LICENSEE may do so and YALE will reasonably cooperate with LICENSEE to execute and deliver to LICENSEE any documents requested by LICENSEE to complete such registration or recordation, at LICENSEE's own expense.

11.3.

12. USE OF NAMES

- Subject to Article 12.3, LICENSEE shall not use the name “Yale” or “Yale University,” nor any variation or adaptation thereof, nor any trademark, tradename or other designation owned by YALE, nor the names of any of its trustees, officers, faculty, students, employees or agents, for any purpose without the prior written consent of YALE in each instance, such consent to be granted or withheld by YALE in its sole discretion, except that LICENSEE may state that it has licensed from YALE one or more patents and/or applications comprising the LICENSED PATENTS.

- Subject to Article 12.3, YALE will not use the name Cassava Sciences, Inc, nor any variation or adaptation thereof, nor any trademark, tradename or other designation owned by LICENSEE, nor the names of any of its trustees, officers, faculty, students, employees or agents, for any purpose without the prior written consent of LICENSEE in each instance, such consent to be granted or withheld by LICENSEE in its sole discretion, except that YALE may state that it has licensed from YALE to LICENSEE one or more patents and/or applications comprising the LICENSED PATENTS.

- The PARTIES will mutually agree on the content and timing of press releases relating to this AGREEMENT and the development of LICENSED PRODUCTS occurring hereunder. Nothing will prevent LICENSEE from issuing press releases or making other publications and presentations relating to LICENSED PRODUCTS that are for a use other than for use in the INDICATION.

13. TERMINATION

- 13.1. YALE shall have the right to terminate this AGREEMENT upon written notice to LICENSEE in the event LICENSEE:
- (a) fails to make any payment whatsoever due and payable pursuant to this Agreement, or any payment that may be due under other contracts with YALE (e.g. sponsored research agreements), unless LICENSEE shall make all such payments (and all interest due on such payments under Section 6.7) within the [***] period after receipt of written notice from YALE; or
 - (b) commits a breach of this AGREEMENT which is not cured (if capable of being cured) within the [***] period after receipt of written notice thereof from YALE, or upon receipt of such notice if such breach is not capable of being cured; or
 - (c) defaults on a material obligation to any other creditor unless LICENSEE shall make all such payments (and all penalties and interests due on such payments) within the [***] period after receipt of written notice from YALE; or

- (d) fails to obtain or maintain adequate insurance as described in Article 14.3, whereupon YALE may terminate this AGREEMENT immediately upon written notice to LICENSEE; or

- (e) if LICENSEE or any of its AFFILIATES brings a PATENT CHALLENGE against YALE, or assists others in bringing a PATENT CHALLENGE against YALE (except as required under a court order or subpoena), and LICENSEE and its AFFILIATES do not withdraw such PATENT CHALLENGE or cease assisting others in bringing such PATENT CHALLENGE within [***] of notice from YALE, then YALE may terminate this Agreement immediately; or

- (f) if a SUBLICENSEE brings a PATENT CHALLENGE or assists another party in bringing a PATENT CHALLENGE (except as required under a court order or subpoena), then YALE may send a written demand to LICENSEE to terminate such SUBLICENSE. If LICENSEE fails to take all steps necessary to so terminate such SUBLICENSE within [***] after YALE's demand, YALE may immediately terminate this Agreement.

13.2. This AGREEMENT shall terminate automatically without any notice to LICENSEE in the event LICENSEE shall cease to carry on its business (or that portion of its business involving LICENSED PRODUCTS) or liquidates a substantial portion of its assets relating to LICENSED PRODUCTS or becomes INSOLVENT, or a petition in bankruptcy is filed against LICENSEE and is consented to, acquiesced in or remains undismissed for [***], or LICENSEE makes a general assignment or assignment of any of its rights hereunder for the benefit of creditors, or a receiver is appointed for LICENSEE.

13.3. LICENSEE shall have the right to terminate this AGREEMENT upon written notice to YALE:

- (a) at any time on [***] notice to YALE, for any or no reason, provided LICENSEE is not in breach and upon payment of all amounts due YALE throughout the effective date of termination; or
- (b) in the event YALE commits a material breach of any of the provisions of this AGREEMENT and such breach is not cured (if capable of being cured) within the [***] period after receipt of written notice thereof from LICENSEE, or upon receipt of such notice if such breach is not capable of being cured.

13.4. (a) Upon termination of this AGREEMENT under Sections 13.1, 13.2 or 13.3(a), all rights and licenses granted to LICENSEE under the terms of this AGREEMENT are terminated. Upon such termination, LICENSEE shall cease to make, have made, use, sell, have sold, distribute, practice, import or export LICENSED PRODUCTS for use or sale. Within [***] of the effective date of termination LICENSEE shall return to YALE:

- (i) all non-public materials relating to or containing the LICENSED PATENTS, LICENSED PRODUCTS or CONFIDENTIAL INFORMATION disclosed by YALE;

- (ii) the last REPORTS required under Article 4 and Article 9; and
 - (iii) all payments incurred up to the effective date of termination.
- (b) Upon expiration of the TERM:
- (i) all rights and licenses granted to LICENSEE under the terms of this AGREEMENT will survive on a fully paid-up and royalty-free basis; and
 - (ii) Articles 8, 10, 11, and 14 will survive.

Termination of this AGREEMENT shall not affect any rights or obligations accrued prior to the effective date of such termination and specifically LICENSEE's obligation to pay all royalties and other payments, including those specified by Articles 5, 6, and 7 that accrued prior to the effective termination date of such termination. In particular, but without limitation, the following provisions shall survive any termination or expiration of this AGREEMENT: Articles 2 and 8, the preservation and inspection obligations of Article 9, Article 12, this Article 13.5, Article 13.6, Article 13.7, Article 14, Article 15, Article 17.1, and Article 18. The PARTIES agree that claims giving rise to indemnification may arise after the TERM or termination of the LICENSE granted herein.

- 13.5. The rights provided in this Article 13 shall be in addition and without prejudice to any other rights, whether at law or in equity, which the parties may have with respect to any default or breach of the provisions of this AGREEMENT.
- 13.6. Waiver by either PARTY of one or more defaults or breaches shall not deprive such PARTY of the right to terminate because of any subsequent default or breach.
- 13.7. As further consideration for the granting of the LICENSE, upon termination of this AGREEMENT under Articles 13.1, 13.2, or 13.3(a):

- (a) LICENSEE shall permit, and require SUBLICENSEES and AFFILIATES to permit, YALE and its future licensees the non-exclusive right to utilize, reference and otherwise have the benefit of regulatory approvals of, or clinical trials or other studies conducted on, and all filings made with regulatory agencies to the extent controlled by LICENSEE and to the extent covering the LICENSED PRODUCTS (but not the API), the sale of which would infringe a VALID CLAIM of a LICENSED PATENT (the "ABANDONED PRODUCTS");

- (b) at YALE's reasonable request, LICENSEE shall deliver to YALE at no expense other than the reasonable cost of duplication and shipping, within [***] of such request all records and grant any additional required access to records that are owned or controlled by LICENSEE, SUBLICENSEE, or an AFFILIATE, and that are required by a REGULATORY AUTHORITY to be maintained with respect to the sale, manufacture, formulation, storage, handling, shipping and use of the ABANDONED PRODUCTS, reimbursement approval files, all documents, data and information related to clinical trials and other studies of ABANDONED PRODUCTS, any other data, techniques, know-how and other information developed or generated that relate to the LICENSED PATENTS or otherwise relate to the ABANDONED PRODUCTS, that are useful for filing of INDs, NDAs, or seeking of MARKETING APPROVAL for such ABANDONED PRODUCTS, but in each case, excluding any of the foregoing that relate solely to the API; and

- LICENSEE shall and hereby does grant YALE a nonexclusive royalty free license under the IMPROVEMENTS to make, have made, manufacture, have manufactured, use, sell, have sold, import, export, or practice ABANDONED PRODUCTS. "IMPROVEMENTS" shall mean any invention or discovery to the extent owned or controlled by LICENSEE as of such termination, conceived by or on behalf of LICENSEE after the EFFECTIVE DATE of the AGREEMENT and (i) that would be infringed or misappropriated by the use, making, selling, offering for sale and importing of such ABANDONED PRODUCTS (but not to the extent covering the API and no other aspect of the ABANDONED PRODUCTS) and (ii) that requires use of that portion of the ABANDONED PRODUCTS that are not the API. Notwithstanding anything to the contrary in the AGREEMENT, LICENSEE would have no obligation to, and does not, license to YALE any of its composition of matter rights in PTI-125 or the API or any successor or similar compound or any rights to exploit PTI-125 or the API. While LICENSEE has the right to reasonably negotiate with YALE or its future licensee for rights in PTI-125, nothing in this AGREEMENT will be construed as obligating LICENSEE to enter into any license or other agreement with YALE or any THIRD PARTY with respect to API that is PTI-125.
- (c)

14. INDEMNIFICATION; INSURANCE; NO WARRANTIES

- LICENSEE shall indemnify, defend by counsel reasonably acceptable to YALE, and hold harmless YALE and its trustees, officers, employees, contractors, grantors, and agents (collectively, "YALE Indemnitees"), from and against any THIRD PARTY claim, liability, cost, expense, damage, deficiency, loss, or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) (collectively, "CLAIMS") against such YALE Indemnitee based upon, arising out of or otherwise relating to this AGREEMENT and arising from an action or inaction by a LICENSEE, including without limitation any cause of action arising from an action or inaction by a LICENSEE and relating to product liability, or any theory of liability (including without limitation tort, warranty, or strict liability) or the death, personal injury, or illness of any person or out of damage to any property related in any way to the rights granted under this
- 14.1. AGREEMENT; or resulting from the production, manufacture, sale, use, lease, or other disposition or consumption or advertisement of the LICENSED PRODUCTS by LICENSEE, its AFFILIATES, SUBLICENSEES or any other transferees; or in connection with any statement, representation or warranty of LICENSEE, its AFFILIATES, SUBLICENSEES or any other transferees with respect to the LICENSED PRODUCTS. LICENSEE shall not settle or compromise the CLAIM without the prior written consent of YALE, such consent not to be unreasonably withheld, conditioned or delayed. Without limiting the foregoing, YALE may withhold its consent to any settlement or compromise that would in any manner constitute or incorporate an admission by any YALE Indemnitee, require any YALE Indemnitee to take or refrain from taking any action, or not include an unconditional release of all YALE Indemnites from all liability for claims that are the subject matter of such settled CLAIM.

LICENSEE shall purchase and maintain in effect and shall require its SUBLICENSEES to purchase and maintain in effect a
14.2. policy of commercial, general liability insurance to protect YALE with respect to events described in Article 14.1. Such insurance shall:

- (a) list “YALE, its trustees, directors, officers, employees and agents” as additional insureds using ISO endorsement CG 2036 10 01 or an equivalent reasonably approved by YALE;
- (b) provide that such policy is primary and not excess or contributory with regard to other insurance YALE may have;
- (c) be endorsed to include product liability coverage in amounts no less [***] per incident and [***] annual aggregate; and
- (d) be endorsed to include contractual liability coverage for LICENSEE’s indemnification under Article 14.1; and
- (e) by virtue of the minimum amount of insurance coverage required under Article 14.2(c), not be construed to create a limit of LICENSEE’s liability with respect to its indemnification under Article 14.1.

By signing this Agreement, LICENSEE certifies that the requirements of Article 14.3 will be met on or before the earlier of
(a) the date of FIRST SALE of any LICENSED PRODUCT or (b) the date any LICENSED PRODUCT is tested or used on
14.4. humans, and will continue to be met thereafter. Upon YALE's request, LICENSEE shall furnish a Certificate of Insurance and a copy of the current insurance policy to YALE. LICENSEE shall secure agreement from its insurer to give [***] written notice to YALE prior to any cancellation of or material change to the policy.

14.5. DISCLAIMER AND LIMITATION OF LIABILITY. EXCEPT TO THE EXTENT EXPRESSLY SET FORTH HEREIN:

- (a) YALE MAKES NO, AND EXPRESSLY DISCLAIMS ALL, REPRESENTATIONS OR WARRANTIES THAT ANY CLAIMS OF THE LICENSED PATENTS, ISSUED OR PENDING, ARE VALID, OR THAT THE MANUFACTURE, USE, PRACTICE, SALE OR OTHER DISPOSAL OF THE LICENSED PRODUCTS DOES NOT OR WILL NOT INFRINGE UPON ANY PATENT OR OTHER RIGHTS NOT VESTED IN YALE.

(b) YALE MAKES NO, AND EXPRESSLY DISCLAIMS ALL, REPRESENTATIONS AND WARRANTIES WHATSOEVER WITH RESPECT TO THE LICENSED PATENTS AND LICENSED PRODUCTS, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

(c) LICENSEE SHALL MAKE NO STATEMENTS, REPRESENTATION OR WARRANTIES WHATSOEVER TO ANY THIRD PARTIES THAT ARE INCONSISTENT WITH THE DISCLAIMERS BY YALE IN ARTICLE 14.4(a) AND 14.4(b).

(d) IN NO EVENT SHALL EITHER PARTY, OR THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER THE OTHER PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

(e) IN NO EVENT SHALL YALE, OR ITS TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES AND AFFILIATES, BE LIABLE FOR DAMAGES IN EXCESS OF AMOUNTS YALE HAS RECEIVED FROM LICENSEE UNDER THIS LICENSE.

14.6. Each of YALE (for 14.6(b) and 14.6(c), to the actual knowledge of Yale Ventures) and LICENSEE hereby represent as of the EFFECTIVE DATE and LICENSEE additionally warrants to the other that, as of the EFFECTIVE DATE:

(a) it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization;

(b) it has the full right, power and authority to enter into this AGREEMENT, to perform its respective obligations under this AGREEMENT and to grant any rights granted to the other PARTY under this AGREEMENT; and

(c) the execution and delivery of this AGREEMENT by such PARTY, the performance of its respective obligations under this AGREEMENT and the grant of any rights granted to the other PARTY under this AGREEMENT do not conflict with, violate, breach or constitute a default under (i) such PARTY'S organizational documents, (ii) any requirement of laws applicable to such PARTY or (iii) any contractual obligations of such PARTY or any of its AFFILIATES existing as of the EFFECTIVE DATE or, except, in each case ((i) through (iii)) for those that would not, individually or in the aggregate, be reasonably expected to have a material adverse effect on the exploitation of the LICENSED PRODUCTS.

14.7. [***]

15.____NOTICES

- 15.1. Any monetary payment, notice or other communication required by this AGREEMENT (a) shall be in writing, (b) may be delivered personally or sent by reputable overnight courier with written verification of receipt or by registered or certified first class United States Mail, postage prepaid, return receipt requested, or by email, (c) shall be sent to the following addresses or to such other address as such party shall designate by written notice to the other party, and (d) shall be effective upon receipt:

FOR YALE:

[***]

[***]

[***]

Cc: [***]

[***]

FOR LICENSEE:

[***]

[***]

[***]

[***]

[***]

and must reference

Yale Agreement No. [***]

16.____INVENTOR AGREEMENTS

- If LICENSEE or an AFFILIATE and any INVENTOR while such INVENTOR is an employee of YALE enter into an INVENTOR AGREEMENT, LICENSEE shall so notify YALE in writing within [***]. The LICENSEE acknowledges and shall require any AFFILIATE to acknowledge that: (i) the INVENTOR is a faculty member, other employee, or student of YALE; (ii) the INVENTOR is subject to certain policies of YALE, as such policies may be revised from time to time, including policies concerning consulting, conflicts of interest, and intellectual property (“YALE POLICIES”); and (iii) to the extent any provision of the INVENTOR AGREEMENT conflicts with YALE POLICIES, or imposes obligations or responsibilities compliance with which would require [***] to act in violation of YALE POLICIES, the provisions of the YALE POLICIES shall prevail. INVENTOR is a third party beneficiary of this paragraph while such INVENTOR is an employee of YALE.
- 16.1.

- LICENSEE or an AFFILIATE shall provide written notice to YALE within [***] after receipt of an invention disclosure in which an employee of YALE is a named as an inventor, and no later than [***] prior to the filing of any patent application of
- 16.2. LICENSEE, SUBLICENSEE, or an AFFILIATE where an employee of YALE is a named as an inventor or claims an invention made while inventor was an employee of YALE. Such disclosure under this Section 16.2 shall be considered CONFIDENTIAL INFORMATION.

16.3. In the event that LICENSEE or an AFFILIATE is granted an assignment by an employee of YALE in violation of YALE POLICIES to an invention made by any employee of YALE without the prior written consent of the Yale Ventures then pursuant to Section 13, YALE shall have the right to terminate this AGREEMENT if such assignment is not corrected by LICENSEE within [***] of written notice from YALE.

16.4. LICENSEE will include Sections 16.1 – 16.3 in each SUBLICENSE (other than to CROs and DISTRIBUTORS who are not otherwise also a SUBLICENSEE) and will include the right to terminate such SUBLICENSE in the event that the applicable SUBLICENSEE breaches such provisions.

17. LAWS, FORUM AND REGULATIONS.

17.1. Any dispute arising out of or related to this AGREEMENT shall be governed by and in accordance with the substantive laws of the State of New York, without regard to its conflicts of law principles, except where the federal laws of the United States are applicable and have precedence. Any dispute arising out of or related to this AGREEMENT shall be brought exclusively in a court of competent jurisdiction in the State of New York's Southern District, and the PARTIES hereby irrevocably submit to the jurisdiction of such courts.

17.2. LICENSEE shall comply, and shall cause its AFFILIATES and SUBLICENSEES to comply, with all foreign and United States federal, state, and local laws, regulations, rules and orders applicable to the testing, production, transportation, packaging, labeling, export, practice, sale and use of the LICENSED PRODUCTS. In particular, LICENSEE shall be responsible for assuring compliance with all United States export laws and regulations applicable to this LICENSE and LICENSEE's activities under this AGREEMENT.

18. MISCELLANEOUS

18.1. This AGREEMENT will be binding upon and inure to the benefit of the parties and their respective legal representatives, successors and permitted assigns.

18.2. This AGREEMENT and the [***] MTA constitute the entire agreement of the PARTIES relating to the LICENSED PATENTS and LICENSED PRODUCTS, and all prior representations, agreements and understandings, written or oral, are merged into it and are superseded by this AGREEMENT and the [***] MTA. Notwithstanding anything to the contrary in this AGREEMENT, nothing in this AGREEMENT is to be construed as amending or otherwise affecting any of the terms or conditions in the [***] MTA and all licenses granted under the [***] MTA continue to remain in full force and effect.

18.3. The provisions of this AGREEMENT shall be deemed separable. If any part of this AGREEMENT is rendered void, invalid, or unenforceable, such determination shall not affect the validity or enforceability of the remainder of this AGREEMENT unless the part or parts which are void, invalid or unenforceable shall substantially impair the value of the entire AGREEMENT as to either party.

18.4. Paragraph headings are inserted for convenience of reference only and do not form a part of this AGREEMENT.

18.5. No PERSON not a party to this AGREEMENT, including any employee of any PARTY to this AGREEMENT, shall have or acquire any rights by reason of this AGREEMENT. Nothing contained in this AGREEMENT shall be deemed to constitute the PARTIES as partners or joint venturers with each other or any THIRD PARTY, and neither PARTY shall be deemed the agent of the other.

18.6. This AGREEMENT may not be amended or modified except by written agreement executed by each of the parties.

18.7. LICENSEE shall have the right to assign this AGREEMENT to an acquiror of all or substantially all of the assets or equity of LICENSEE, whether by asset purchase, equity purchase, merger or other transaction and whether as one transaction or a series of transactions..

18.8. [RESERVED]

18.9. The failure of any PARTY hereto to enforce at any time, or for any period of time, any provision of this AGREEMENT shall not be construed as a waiver of either such provision or of the right of such PARTY thereafter to enforce each and every provision of this AGREEMENT.

18.10. This AGREEMENT may be executed in any number of counterparts and any PARTY may execute any such counterpart, each of which when executed and delivered shall be deemed to be an original and all of which counterparts taken together shall constitute but one and the same instrument.

18.11. The terms and conditions of this AGREEMENT shall, at YALE's sole option, be considered by YALE to be withdrawn from LICENSEE's consideration and the terms and conditions of this AGREEMENT, and the AGREEMENT itself to be null and void, unless this AGREEMENT is executed by the LICENSEE and a fully executed AGREEMENT is received by YALE within [***] from the date of the YALE signature found at the Signature Page.

Signature Page, Appendices, and Exhibits Follow

Page [***] of 44

Signature Page

IN WITNESS to their AGREEMENT, the PARTIES have caused this AGREEMENT to be executed in duplicate originals by their duly authorized representatives.

YALE UNIVERSITY

CASSAVA SCIENCES, INC.

By:/s/
[***] _____

By: /s/Richard J.
Barry _____

Name: [***]

Name: Richard J. Barry

Title: [***]

Title: President & Chief Executive Officer

Date:February 26,
2025 _____

Date:February 26,
2025 _____

Appendix A: LICENSED PATENTS and LICENSED INFORMATION

Appendix A1: LICENSED PATENTS

Yale REF:	Patent Title	Status	Country	App Type	Appl /Patent#	Patent Expiration Date
***	***	***	***	***	***	8/13/2021
***	***	***	***	***	***	2/13/2040
***	***	***	***	***	***	8/13/2021
***	***	***	***	***	***	2/13/2040
***	***	***	***	***	***	8/13/2021
***	***	***	***	***	***	2/13/2040

Appendix A2: Summary of LICENSED INFORMATION

[***]

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Appendix B: PLAN

[***]

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CONFIDENTIAL

Exhibit 6.7 Wire Transfer Instructions

[***]

Page [***] of 44

CONFIDENTIAL

Exhibit 9.1 Report Form

[***]

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Cassava Sciences Licenses Simufilam Method of Treatment Patent

- *Cassava enters into a license agreement with Yale University granting intellectual property rights, including rights to an issued US method of treatment patent for potential treatment with simufilam of seizures related to rare neurodevelopmental disorders*
- *The licensed patent is based on research led by Yale University and published in Science Translational Medicine showing that treatment with simufilam appeared to meaningfully reduce seizure frequency in an animal model*
- *Cassava will prioritize initial development efforts on tuberous sclerosis complex (TSC)-related seizures*

AUSTIN, Texas (GLOBE NEWSWIRE) – February 27, 2025 – Cassava Sciences, Inc. (NASDAQ: SAVA, “Cassava”, the “Company”), a clinical-stage biotechnology company focused on developing novel, investigational treatments for central nervous system (CNS) disorders, today announced that it has entered into an agreement with Yale University (Yale) for a license to intellectual property rights, including an exclusive license to an issued US method of treatment patent (US 12,186,307¹) for simufilam as a potential treatment for seizures related to rare neurodevelopmental disorders including tuberous sclerosis complex (TSC). Simufilam is Cassava’s proprietary small molecule drug candidate that targets filamin A.

The intellectual property that Cassava has licensed is based on the promising research and development work of Angélique Bordey, PhD, Professor of Neurosurgery and Vice Chair of Research, Neurosurgery at Yale, and her collaborators. In a paper published in *Science Translational Medicine*² in 2020, the researchers showed that treatment with simufilam (also known as PTI-125) appeared to meaningfully reduce TSC-related seizure frequency in an animal model. These data formed the basis of the US method of treatment patent issued to Yale on January 7, 2025¹, which is included in the license to Cassava.

“We are pleased to enter into a license agreement with Yale University, based on the research of Dr. Angélique Bordey and her team. Dr. Bordey’s research opens the door to a potential new therapeutic application for simufilam in the treatment of seizures related to rare neurodevelopmental disorders, including tuberous sclerosis complex,” said Rick Barry, President and Chief Executive Officer of Cassava Sciences. “We plan to conduct preclinical studies in collaboration with the TSC Alliance to further evaluate simufilam’s potential as a treatment for TSC-related seizures and define next steps.”

About Simufilam

Simufilam is a proprietary, investigational oral small molecule that targets the filamin A protein.

About TSC

Tuberous sclerosis complex (TSC) and focal cortical dysplasia (FCD) type II are neurodevelopmental disorders caused by mutations in the mechanistic target of rapamycin (mTOR) pathway genes. These mutations lead to focal malformations of the developing cortex and seizures in 80% to 90% of patients.

Nearly two-thirds of TSC patients do not respond to antiepileptic drugs and experience lifelong seizures, leading to a spectrum of neurocognitive and psychological disabilities and poor quality of life. Current treatments, including antiepileptic drugs, mTOR analogs and surgery, are not fully effective, are associated with serious adverse events and/or are invasive.²

Initially, Cassava will focus on developing simufilam as a potential treatment for TSC-related seizures. According to the TSC Alliance, the disorder affects an estimated 1 in 6,000 live births. Approximately 50,000 people in the United States and more than one million worldwide live with TSC³.

Resources:

1. *US Patent 12,186,307 B2*
2. *Science Translational Medicine*. 2020 Feb 19: <https://pubmed.ncbi.nlm.nih.gov/32075941/>
3. <https://www.tscalliance.org/understanding-tsc/what-is-tsc/>

About Cassava Sciences, Inc.

Cassava Sciences, Inc. (NASDAQ: SAVA), is a clinical-stage biotechnology company focused on developing novel, investigational treatments for central nervous system disorders, including Alzheimer's disease and tuberous sclerosis complex (TSC)-related seizures. Simufilam is a proprietary, investigational oral small molecule that targets the filamin A protein. The Company is based in Austin, Texas.

For more information, please visit: <https://www.CassavaSciences.com>

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Cautionary Note Regarding Forward-Looking Statements:

This news release contains forward-looking statements that include but are not limited to statements regarding: the plan to conduct preclinical studies of simufilam relating to TSC-related epilepsy, opportunities for simufilam with respect to other neurodevelopmental disorders, the potential for simufilam as a treatment for TSC-related seizures and Cassava's development priorities. These statements may be identified by words such as "anticipate", "before," "believe", "could", "expect", "forecast", "intend", "may", "pending", "plan", "possible", "potential", "prepares for", "will", and other words and terms of similar meaning.

Such statements are based on our current expectations and projections about future events. Such statements speak only as of the date of this news release and are subject to a number of risks, uncertainties and assumptions, including, but not limited to, those risks relating to the ability to conduct or complete preclinical and clinical studies on expected timelines and the results of such studies; and other risks inherent in drug discovery and development or specific to Cassava Sciences, Inc., as described in the section entitled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and Quarterly Report on Form 10-Q for the period ended September 30, 2024, and future reports to be filed with the SEC. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from expectations in any forward-looking statement. In light of these risks, uncertainties and assumptions, the forward-looking statements and events discussed in this news release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Except as required by law, we disclaim any intention or responsibility for updating or revising any forward-looking statements. For further information regarding these and other risks related to our business, investors should consult our filings with the SEC, which are available on the SEC's website at www.sec.gov.

All of our pharmaceutical assets under development are investigational product candidates. These have not been approved for use in any medical indication by any regulatory authority in any jurisdiction and their safety, efficacy or other desirable attributes, if any, have not been established in any patient population. Consequently, none of our product candidates is approved or available for sale anywhere in the world.

Our clinical results from preclinical studies and earlier-stage clinical trials may not be indicative of future results from later-stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or any scientific data we present or publish.

We are in the business of new drug discovery, development and commercialization. Our research and development activities are long, complex, costly and involve a high degree of risk. Holders of our common stock should carefully read our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q in their entirety, including the risk factors therein. Because risk is fundamental to the process of drug discovery, development and commercialization, you are cautioned to not invest in our publicly traded securities unless you are prepared to sustain a total loss of the money you have invested.

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**Document And Entity
Information**

Feb. 27, 2025

Document Information [Line Items]

<u>Entity, Registrant Name</u>	Cassava Sciences, Inc.
<u>Document, Type</u>	8-K
<u>Document, Period End Date</u>	Feb. 27, 2025
<u>Entity, Incorporation, State or Country Code</u>	DE
<u>Entity, File Number</u>	001-41905
<u>Entity, Tax Identification Number</u>	91-1911336
<u>Entity, Address, Address Line One</u>	6801 N Capital of Texas Highway
<u>Entity, Address, Address Line Two</u>	Building 1; Suite 300
<u>Entity, Address, City or Town</u>	Austin
<u>Entity, Address, State or Province</u>	TX
<u>Entity, Address, Postal Zip Code</u>	78731
<u>City Area Code</u>	512
<u>Local Phone Number</u>	501-2444
<u>Written Communications</u>	false
<u>Soliciting Material</u>	false
<u>Pre-commencement Tender Offer</u>	false
<u>Pre-commencement Issuer Tender Offer</u>	false
<u>Title of 12(b) Security</u>	Common Stock
<u>Trading Symbol</u>	SAVA
<u>Security Exchange Name</u>	NASDAQ
<u>Entity, Emerging Growth Company</u>	false
<u>Amendment Flag</u>	false
<u>Entity, Central Index Key</u>	0001069530

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