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

#### FORM 10-Q

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

For the quarterly period ended September 30, 2014 or

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

For the transition period from \_\_\_\_\_to\_\_\_\_

Commission file number: 001-35005

#### ASSEMBLY BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

**20-8729264** (I.R.S. Employer Identification No.)

**99 Hudson Street, 5th Floor, New York, New York 10013** (Address of principal executive offices, including zip code)

(646) 706-5208

(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES  $\boxtimes$  NO  $\square$ 

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

Large Accelerated FilerAccelerated FilerINon-accelerated FilerI(Do not check if smaller reporting company)Smaller Reporting CompanyI

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES 🗆 NO 🗵

As of November 10, 2014, there were 10,647,059 shares of registrant's common stock outstanding.

### PART I – FINANCIAL INFORMATION

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### CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2014			December 31, 2013
		(unaudited)		
ASSETS				
Current assets				
Cash and cash equivalents	\$	17,932,627	\$	27,061,268
Other current assets		147,178		63,672
Total current assets		18,079,805		27,124,940
Computer equipment, net		34,084		7,102
Intangible assets		30,137,350		-
Goodwill		12,142,702		-
Total assets	\$	60,393,941	\$	27,132,042
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities				
Accounts payable and accrued expenses	\$	1,049,019	\$	2,638,054
Total current liabilities	<u> </u>	1,049,019	<u>+</u>	2,638,054
Deferred tax liabilities		12,142,702		
Total liabilities		13,191,721		2,638,054
		13,191,721		2,030,034
Stockholders' deficit				
Preferred stock, \$0.001 par value; 5,000,000 shares authorized; Series A non-voting convertible				
preferred stock: 0 and 44,000 issued and outstanding at September 30, 2014 and December 31, 2013, respectively		_		44
Common stock, \$0.001 par value; 50,000,000 shares authorized; 8,688,099 shares and 4,146,779				
shares issued, and outstanding at September 30, 2014 and December 31, 2013, respectively		8,688		4,147
Additional paid-in capital		176,107,503		135,844,320
Common stock issuable, 25,000 shares at at September 30, 2014 and December 31, 2013		368,750		368,750
Accumulated deficit		(129,282,721)		(111,723,273)
Total stockholders' deficit		47,202,220		24,493,988
Total liabilities and stockholders' deficit	\$	60,393,941	\$	27,132,042

See Notes to Condensed Consolidated Financial Statements

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	T	Three Months Ended September 30,				Nine Months End	ed Se	ptember 30,
		2014		2013		2014		2013
Operating expenses:								
Research and development		3,671,983		3,753,319		7,741,317		9,870,871
General and administrative		7,383,457		1,179,689		9,930,418		3,639,863
Total operating costs and expenses		11,055,440		4,933,008		17,671,735		13,510,734
Loss from operations		(11,055,440)		(4,933,008)		(17,671,735)		(13,510,734)
Other income								
Interest income		35,182		51,266		112,287		154,009
Total other income		35,182		51,266		112,287		154,009
Net loss	\$	(11,020,258)	\$	(4,881,742)	\$	(17,559,448)	\$	(13,356,725)
Net loss per share, basic and diluted	\$	(1.33)	\$	(1.23)	\$	(3.02)	\$	(3.53)
Weighted average common shares outstanding, basic and diluted		8,277,355		3,978,905		5,814,316		3,780,343
See Notes to C	Condens	ed Consolidated I	Financ	ial Statements				

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Months Ended September 30,			ember 30,
		2014		2013
Cash flows from operating activities				
Net loss	\$	(17,559,448)	\$	(13,356,725)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		3,894		4,375
Stock-based compensation		8,002,033		1,451,688
Issuance of warrants for services		679,447		-
Changes in assets and liabilities:				
Other current assets		(43,360)		(75,196)
Accounts payable and accrued expenses		(2,463,148)		(427,798)
Net cash used in operating activities		(11,380,582)		(12,403,656)
Cash flows from investing activities				
Purchase of fixed assets		(20,526)		(5,166)
Cash acquired in business combination		509,363		-
Net cash provided by (used in) investing activities	· · · · · · · · · · · · · · · · · · ·	488,837		(5,166)
		· · · · ·		
Cash flows from financing activities				
Proceeds from issuance of common stock		1,763,104		24,142,513
Net cash provided by financing activities		1,763,104		24,142,513
				<u> </u>
Net (decrease) increase in cash		(9,128,641)		11,733,691
Cash at the beginning of the period		27,061,268		20,489,219
Cash at the end of the period	\$	17,932,627	\$	32,222,910

See Notes to Condensed Consolidated Financial Statements

### CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued) (UNAUDITED)

	Nine Months Ended September 30,			
	 2014		2013	
Supplemental disclosure of non-cash activities:				
Assembly business combination				
Other current assets	\$ (40,146)	\$		-
Equipment, net	(10,350)			-
Intangible assets	(30,137,350)			-
Goodwill	(12,142,702)			-
Accounts payable and accrued expenses	874,113			-
Common stock issued	29,064,148			
Fair value of options assumed	758,948			-
Deferred tax liability	12,142,702			-
Cash acquired in business combination	\$ 509,363	\$		-
Conversion of preferred stock to common stock	\$ 440	\$		-

See Notes to Condensed Consolidated Financial Statements

# CONDENSED CONSOLDATED STATEMENTS OF CHANGE IN STOCKHOLDERS' EQUITY (UNAUDITED)

### For the nine months ended September 30, 2014

	Commo	n Ste	ock	Preferre	d St	ack	Additional	Common Stock	Accumulated	Total Stockholders'
	Commo	1 50			u St	UCK	Paid-in	Stock	Accumulated	Stockholders
	Shares	Aı	nount	Shares	A	mount	Capital	Issuable	Deficit	Equity
Balance as of December 31, 2013	4,146,779	\$	4,147	44,000	\$	44	\$135,844,320	\$ 368,750	\$ (111,723,273)	\$ 24,493,988
Issuance of common stock for										
cash	92,472		92	-		-	1,763,012	-	-	1,763,104
Issuance of common stock for										
business combination	4,008,848		4,009	-		-	29,060,139			29,064,148
Conversion of preferred stock to										
common stock	440,000		440	(44,000)		(44)	(396)	-	-	-
Fair value of options assumed	-		-	-		-	758,948	-	-	758,948
Issuance of warrants for services	-		-	-		-	679,447			679,447
Stock-based compensation	-		-	-		-	8,002,033	-	-	8,002,033
Net loss	-		-	-		-	-	-	(17,559,448)	(17,559,448)
Balance as of September 30, 2014	8,688,099	\$	8,688		\$	-	\$176,107,503	\$ 368,750	\$(129,282,721)	\$ 47,202,220

See Notes to Condensed Consolidated Financial Statements

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### Note 1 - Overview and Basis of Presentation:

Assembly Biosciences, Inc. ("Assembly" or the "Company") (formerly known as Ventrus Biosciences, Inc.) is a biopharmaceutical company committed to applying its scientific knowledge in the field of infectious diseases to transform lives by discovering treatments for patients with Hepatitis B virus ("HBV") and clostridium difficile ("CDAD").

On July 11, 2014, the Company's wholly-owned subsidiary merged with and into Assembly Pharmaceuticals, Inc. (the "Assembly Merger"), with Assembly Pharmaceuticals, Inc. ("Assembly Pharmaceuticals") as the surviving entity. In connection with the Assembly Merger, on July 11, 2014, the Company changed its name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc.

The target of Assembly's lead program is a clinical cure for HBV. Assembly has discovered a series of new compounds, known as core protein allosteric modulators, or CpAMs, that are capable of targeting and altering certain key proteins of HBV. These core proteins are involved in several steps of the HBV lifecycle and are essential for HBV's continued regeneration and survival. Modulation of these core proteins with Assembly's CpAMs has demonstrated preclinical proof of principle: multiple cell models have shown that CpAMs can selectively reduce the production of viral antigens—viral proteins responsible for common symptoms related to HBV, as well as reduce viral load—infectious viral particles circulating in the bloodstream.

Assembly's second lead program, VEN 310, is based on a novel coating and encapsulation technology that allows for targeted delivery of complex agents to select regions of the gastrointestinal ("GI") tract. This delivery platform aims to deliver several types of beneficial specific bacteria to the GI tract. The technology builds upon experience reported in the literature of treating CDAD with fecal material transplant ("FMT") and seeks a path for potentially curative therapy using a targeted and specific microbiome therapy in an oral capsule.

The Company's condensed consolidated financial statements include the Company's accounts and the accounts of the Company's wholly-owned subsidiary, Assembly Pharmaceuticals, from the date of Assembly Merger. All intercompany transactions have been eliminated in consolidation. The condensed consolidated interim financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

The accompanying condensed balance sheet as of December 31, 2013, which has been derived from the Company's audited financial statements, and the unaudited interim condensed consolidated financial statements, have been prepared in accordance with GAAP and the rules and regulations of the Securities and Exchange Commission ("SEC") related to a quarterly report on Form 10-Q. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations, although the Company believes that the disclosures made are adequate to make the information presented not misleading. The unaudited interim consolidated financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair presentation of the results for the periods presented. All such adjustments are of a normal and recurring nature. These unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 31, 2014. The operating results presented in these unaudited condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### Note 2 - Summary of Significant Accounting Policies and Recent Accounting Pronouncements:

#### Goodwill and Other Intangible Assets

Goodwill is the excess of purchase price over the fair value of identified net assets of businesses acquired. The Company's intangible assets with an indefinite life are related to in-process research and development ("IPR&D") programs acquired in the Assembly Merger, as the Company expects future research and development on these programs to provide the Company with substantial benefit for a period that extends beyond the foreseeable horizon. Intangible assets with indefinite useful lives are measured at their respective fair values as of the acquisition date. The Company does not amortize goodwill and intangible assets with indefinite useful lives. Intangible assets related to IPR&D projects are considered to be indefinite- lived until the completion or abandonment of the associated R&D efforts. If and when development is complete, which generally occurs if and when regulatory approval to market a product is obtained, the associated assets would be deemed finite- lived and would then be amortized based on their respective estimated useful lives at that point in time.

The Company reviews goodwill and indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit or the indefinite-lived intangible assets below their carrying values. The Company tests its goodwill and indefinite-lived intangible assets below their carrying values. The Company tests its goodwill and indefinite-lived intangible assets each year on December 31. The Company reviews the carrying value of goodwill and indefinite-lived intangible assets utilizing a discounted cash flow model, and, where appropriate, a market value approach is also utilized to supplement the discounted cash flow model. The Company makes assumptions regarding estimated future cash flows, discount rates, long-term growth rates and market values to determine each reporting unit's estimated fair value

#### **Business Combinations**

The Assembly Merger was made at a price above the fair value of the assets acquired and liabilities assumed including deferred tax liability, resulting in goodwill, based on the Company's expectations of synergies and other benefits of combining the acquired business. These synergies and benefits include elimination of redundant functions and staffing and use of the Company's existing infrastructure to expand development of the product candidates of the acquired business in a cost efficient manner.

Significant judgment is required in estimating the fair value of intangible assets and in assigning their respective useful lives. The fair value estimates are based on available historical information and on future expectations and assumptions deemed reasonable by management, but which are inherently uncertain.

Net assets acquired are recorded at their fair value and are subject to adjustment upon finalization of the fair value analysis. The Company is not aware of any information that indicates the final fair value analysis will differ materially from the preliminary estimates.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The ASU provides for a single comprehensive model for use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance. The accounting standard is effective for interim and annual periods beginning after December 15, 2016 with no early adoption permitted. The Company is currently in the process of evaluating the impact of the guidance on its financial position, results of operation, and cash flows.

In June 2014, the FASB issued ASU 2014-10, *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation.* The amendments in this update remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from GAAP. In addition, the amendments eliminate the requirements for development stage entities to (1) present inception-to-date information in the statements of income, cash flows and shareholder equity, (2) label the financial statements as those of a development stage entity, (3) disclose a description of the development stage activities in which the entity is engaged, and (4) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. A public entity is required to apply the amendments for annual reporting periods beginning after December 15, 2014, and interim periods therein. An entity should apply the amendments retrospectively for all comparative periods presented. Early adoption is permitted. The guidance was adopted by the Company in the second quarter of 2014. Adoption of this standard did not have a material impact on the Company's financial position, statement of operations, or statement of cash flows.

In June 2014, the FASB issued ASU 2014-12, *Compensation—Stock Compensation (Topic 718)*. The ASU clarifies how entities should treat performance targets that can be achieved after the requisite service period of a share-based payment award. The accounting standard is effective for interim and annual periods beginning after December 15, 2015. The Company is currently in the process of evaluating the impact of the guidance on its financial position, results of operation, and cash flows.

The FASB has issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* The guidance, which is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted, extends the responsibility for performing the going-concern assessment to management and contains guidance on how to perform a going-concern assessment and when going-concern disclosures would be required under GAAP. The Company is currently evaluating the impact of this ASU on its condensed consolidated financial statements.

Accounting standards that have been issued by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption. There have been no other material changes to the significant accounting policies previously disclosed in the Annual Report on Form 10-K for the year ended December 31, 2013.

#### Note 3 – Assembly Pharmaceuticals, Inc. Transaction:

On July 11, 2014, the Company completed the Assembly Merger, whereby Assembly Pharmaceuticals became the Company's wholly-owned subsidiary. Pursuant to the terms of the Assembly Merger, the shares of Assembly Pharmaceuticals were converted into an aggregate of 4,008,848 shares of the Company's common stock. Also pursuant to the terms of the Assembly Merger, the options to purchase shares of Assembly Pharmaceuticals were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company's common stock.



### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

The preliminary allocation of the purchase price to the Assembly balance sheet is shown below:

Cash and cash equivalents	\$ 509,363
Other current assets	40,146
Equipment	10,350
Intangible assets	30,137,350
Goodwill	12,142,702
Total assets	 42,839,911
Accrued expenses	874,113
Deferred tax liability	12,142,702
Total liabilities	 13,016,815
Net assets acquired	\$ 29,823,096

The transaction was accounted for using the acquisition method. Accordingly, goodwill has been measured as the excess of the total consideration over the amounts assigned to the identifiable assets acquired and liabilities assumed including the related deferred tax liability.

On the acquisition date, the fair value of net assets acquired was 17,680,148. The fair value of stock issued to the Assembly Pharmaceuticals shareholders as part of the consideration of 29,064,148 was based on reference to quoted market values of the Company's common stock as of the date of acquisition. The options assumed in the Assembly Merger were valued at approximately 758,948 using the Black-Scholes model. The fair value of the options was recorded as a component of stockholders' equity. The fair value of the options was determined using the Black-Scholes model with the following assumptions: risk free interest rate -1.66% - 2.15%, volatility -97.33% - 102.80%, expected term -5 - 6.10 years, expected dividends– N/A.

The fair value of the net assets acquired in the Assembly Merger is preliminary and is subject to change over the upcoming periods.

#### Note 4 - Goodwill:

In July 2014, the Company completed its acquisition of Assembly Pharmaceuticals (Note 3). The fair value of consideration paid, common stock and assumed options, totaled \$29,823,096, which net of amounts allocated to assets and liabilities acquired at fair value, resulted in a preliminary allocation to goodwill of \$12,142,702. The Company only has one operating segment.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Goodwill is recorded as an indefinite-lived asset and is not amortized for financial reporting purposes but is tested for impairment on an annual basis or when indications of impairment exist. No goodwill impairment losses have been recognized. Goodwill is not deductible for income tax purposes since the tax basis is \$0. The Company will perform its annual impairment test of the carrying value of the Company's goodwill each year on December 31.

No goodwill existed as of December 31, 2013. The change in the net book value of goodwill from December 31, 2013 to September 30, 2014 is shown in the table below:

As of December 31, 2013	\$ -
Acquisitions	12,142,702
As of September 30, 2014	\$ 12,142,702

#### Note 5 – Intangible assets, net:

In July 2014, the Company completed its acquisition of Assembly Pharmaceuticals (Notes 1, 3). The Company acquired certain indefinite lived intangible assets related to Assembly Pharmaceuticals' technology.

No intangible assets existed as of December 31, 2013. The change in intangible assets from December 31, 2013 to September 30, 2014 is shown in the table below:

As of December 31, 2013	\$ -
Acquisitions - IPR&D	30,137,350
As of September 30, 2014	\$ 30,137,350

#### Note 6 - Stockholders' Equity:

#### **Reverse Stock Split:**

The Company's Board of Directors and stockholders approved a 1-for-5 reverse stock split of the Company's common stock. The reverse stock split became effective on July 11, 2014. All share and per share amounts in the condensed consolidated interim financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

#### **Assembly Merger:**

On July 11, 2014, the Company completed the Assembly Merger, whereby Assembly Pharmaceuticals became the Company's wholly-owned subsidiary. Pursuant to the terms of the Assembly Merger, the shares of Assembly Pharmaceuticals, common stock issued and outstanding were converted into an aggregate of 4,008,848 shares of the Company's common stock. Also pursuant to the terms of the Assembly Merger, the options to purchase shares of Assembly Pharmaceuticals, common stock issued and outstanding immediately prior to the Assembly Merger were assumed by the Company and became exercisable for an aggregate of 621,651 shares of the Company's common stock. The fully vested assumed options in the Assembly Merger were valued at \$758,948 using the Black-Scholes model. The fair value of the options was recorded as a component of stockholders' equity. The fair value of the options was determined using the Black-Scholes model with the following assumptions: risk free interest rate – 1.66% - 2.15%, volatility – 97.33% - 102.8%, expected term 5 - 6.1 years, expected dividends– N/A.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### **Shelf Registration Statement:**

On February 10, 2012, the Company's shelf registration statement was declared effective by the SEC. From May 2012 through December 2013, the Company sold an aggregate of 1,630,849 shares of common stock and 44,000 shares of Series A Non-Voting Preferred Stock, convertible into 440,000 shares of common stock, under the shelf, resulting in net proceeds of approximately \$28,566,000. In January 2014, the Company sold an aggregate of 92,472 shares of common stock under the amended at-the-market common equity sales program, resulting in net proceeds of approximately \$1,763,000. In October 2014, the Company sold an aggregate of 1,959,000 shares of common stock under the shelf, resulting in net proceeds of approximately \$14,900,000 (see Note 10). The Company does not anticipate selling any more shares under this shelf registration statement.

#### **Options, Warrants and Restricted Stock Units:**

#### **Options**

The Company has two equity incentive plans available for the granting of equity awards. In July 2010, the stockholders approved the 2010 Stock Plan, under which, as of September 30, 2014, there were outstanding options for an aggregate of 18,000 shares of common stock and an aggregate of 726,792 shares available for grant. In July 2014, the stockholders approved the 2014 Stock Incentive Plan, under which, as of September 30, 2014, there were options for an aggregate of 2,560,000 shares of common stock outstanding and no shares available for grant.

Through July 10, 2014, an aggregate of 57,953 options were forfeited and on July 10, 2014, all of the Company's directors and employees forfeited an additional aggregate of 514,445 options. Through July 10, 2014 an aggregate of 122,700 options to acquire the Company's Common Stock was granted to employees. Also on July 10, 2014, Company's stockholders approved the 2014 Stock Incentive Plan, under which an aggregate of 2,560,000 shares of the Company granted all of these options to various employees and directors with an exercise price of \$7.20 and which vest one third on the date of grant, one third on the first anniversary of the option grant date and one third on the second anniversary of the option grant date. The cancellation and reissuance of these stock options was treated as a modification and, accordingly, total stock-based compensation expense related to these awards increased \$15,003,740, which will be recognized over the new vesting period. The options assumed on the Assembly Merger are outside the Company's stock option plans. Option expense this quarter relating to options granted on July 11, 2014 was \$6,752,089.

A summary of the Company's option activity and related information is as follows:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value as at September 30, 2014
Outstanding as of December 31, 2013	467,698	\$ 29.35	\$-
Assumed	621,651	2.22	3,711,256
Granted	2,682,700	7.74	2,534,400
Forfeited	(572,398)	27.22	-
Outstanding as of September 30, 2014	3,199,651	\$ 6.27	\$ 6,245,656
Options vested and exercisable	1,048,087	\$ 6.42	\$ 1,891,627

The fair value of the options granted for the nine-month period ended September 30, 2014, was based on the following assumptions:

	For the Nine Months ended September 30, 2014
Exercise price	\$2.22 - \$15.75
Expected stock price volatility	97.3% - 105.0%
Risk-free rate of interest	1.66% - 2.57%
Term (years)	4.9 - 10.0
12	

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Estimated future stock-based compensation expense relating to unvested stock options is as follows:

		uture Stock Option
	Compensation	
		Expenses
Three months ended 2014	\$	2,371,612
2015		6,040,120
2016		1,595,568
Total	\$	10,007,300

The weighted average remaining contractual life of options outstanding at September 30, 2014 is approximately 9.7 years. Stock-based compensation expensed to research and development expense for the three and nine months ended September 30, 2014 and 2013 was \$1,926,473 and \$2,000,449 (including reversal of charges related to unvested options which were forfeited and for which new options were not issued) and \$152,726 and \$500,830, respectively. Stock-based compensation expensed to general and administrative expense for the three and nine months ended September 30, 2014 and 2013 was \$5,508,048 and \$6,001,584 and \$297,197 and \$950,858, respectively.

#### Warrants

In connection with the Company's financings from 2007 to 2010, the Company issued warrants to investors and/or placement agents to purchase shares of common stock as well as certain consultants. In connection with the Assembly Merger, the Company issued warrants to purchase up to 120,265 shares of its common stock to its financial advisor for the Assembly Merger. The warrants were valued at \$679,447 and expensed during the quarter ended September 30, 2014.

A summary of the Company's warrant activity and related information is as follows:

	Warrants	Weighted Average Exercise Price	
Outstanding as of December 31, 2013	172,209	\$ 38.8	5
Issued	120,265	5.1	3
Expired	(20,973)	33.0	0
Outstanding as of September 30, 2014	271,501	\$ 24.3	7
Exercisable as of September 30, 2014	271,501	\$ 24.3	7

#### Restricted Stock Units

On April 5, 2013, the Company granted restricted stock units to four employees under the 2010 Plan for an aggregate of 100,000 shares of common stock. Of these units, 25% vested immediately at the grant date and was expensed. The remaining 75% of the units were forfeited on July 10, 2014 and the holders received options (see options above).

A summary of the status of our restricted stock units as of September 30, 2014 is as follows:

	Average
Exe	rcise Price
00 \$	10.20
)0)	10.20
- \$	-
0	000) - <u>\$</u>

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### Note 7 - License Agreements:

#### HBV Research Agreement with Indiana University

The Company, through its wholly-owned subsidiary, Assembly Pharmaceuticals, is party to a license agreement with Indiana University Research and Technology Corporation ("IURTC") from whom it has licensed the Company's HBV therapy. The license agreement requires the Company to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to the HBV therapy. The total amount of all potential future milestone payments at September 30, 2014 is \$825,000. The Company also is obligated to pay IURTC royalty payments based on net sales of the licensed technology, which increase if the Company sublicenses its rights to a non-affiliate third party. The Company is also obligated to pay diligence maintenance fees (starting at \$25,000 in 2014 and rising to \$100,000 in the year following first commercial sale of licensed product) each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year.

#### Microbiome Targeted Colonic Delivery Platform

On November 8, 2013, Assembly entered into a License and Collaboration Agreement with Therabiome, LLC, for all intellectual property and know-how owned or controlled by Therabiome relating to the oral delivery of pharmaceutical drugs to specific sites in the intestine, using a pH sensitive controlled release platform technology. Under the agreement, Therabiome granted to Assembly the exclusive worldwide license, with rights to sublicense, to develop the intellectual property for commercialization (a) in the use of bacteria, viruses, proteins and small molecules by oral delivery in (i) gastro- intestinal dysbiosis, including but not limited to C. difficile, irritable bowel syndrome-constipation and inflammatory bowel disease, (ii) auto-immune disorders and autism, including but not limited to as controlled by bacteria or virus, and (iii) orally delivered vaccines, including viral and bacterial, and (b) any oral delivery of small molecules using the licensed intellectual property. Assembly will be solely responsible for all research and development activities with respect to any product it develops under the license.

For the license, Assembly paid Therabiome an upfront non-refundable license fee of \$300,000. Assembly must pay Therabiome clinical and regulatory milestones for each product or therapy advanced from the platform for U.S. regulatory milestones. Assembly also must pay Therabiome lesser amounts for foreign regulatory milestones, which vary by country and region. Assembly also must pay Therabiome royalties on annual net sales of a product in the low to mid-single digit percentages plus, once annual net sales exceed two certain thresholds, a one-time cash payment upon reaching each threshold.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Therabiome must pay Assembly royalties on annual net sales of any product it develops, using the intellectual property, in the low double to middouble digit percentages, depending on the level of development or involvement Assembly had in the product.

#### Diltiazem (VEN 307) and Phenylepherine (VEN 308)

At September 30, 2014, the Company had an exclusive royalty-bearing license agreement with S.L.A. Pharma, AG ("S.L.A. Pharma") to sell, make and use diltiazem (VEN 307) for treatment, through topical administration, of anal fissures and phenylepherine (VEN 308) for treatment, through topical administration, of fecal incontinence (referred to collectively as the "Compound Technologies") in the United States, Canada and Mexico. In the event that the Compound Technologies were commercialized, Assembly was obligated to pay to S.L.A. Pharma annual royalties, based upon net sales of the products. In addition, Assembly was required to make payments to S.L.A. Pharma up to an aggregate amount of \$20 million upon the achievement of various milestones related to regulatory events.

On July 24, 2014, the Company notified S.L.A. Pharma that it was terminating the license agreement. The termination was effective on October 22, 2014. There were no early termination penalties as a result of the termination and the Company has no continuing obligation to make payment to S.L.A. Pharma under the agreement. The Company terminated the agreement to focus on the development of its potentially curative programs for HBV, which program was acquired on July 11, 2014 in the merger with Assembly Pharmaceuticals, Inc., and CDAD, which was licensed in November 2013 from Therabiome, LLC.

#### Note 8 - Commitments:

#### **Employment Agreements:**

On January 15, 2014, the Company entered into an employment agreement with its Chief Executive Officer and its Chief Financial Officer, with an effective date of December 22, 2013. Each agreement has a term of two years and will be automatically extended for additional one-year periods unless the Company notifies the officer at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The employment agreements provide for a base salary of \$475,000 per year for the Chief Executive Officer and \$300,000 for the Chief Financial Officer, and an annual discretionary bonus of up to 50% of the officer's base salary based on financial, clinical development and business milestones established by the Board of Directors. In connection with the Assembly Merger, the Company amended the Chief Executive Officer's employment agreement. Pursuant to the amendment, the Chief Executive Officer will continue to serve as the Company's Chief Executive Officer. However, after the Assembly Merger, at any time the Company's Board may appoint the Company's President and Chief Operating Officer as Chief Executive Officer. In such event, the Chief Executive Officer will become the Executive Chair, and his employment as Chief Executive Officer will end.

In connection with the Assembly Merger, effective July 11, 2014, the Company entered into employment agreements with its President and Chief Operating Officer, its Chief Medical Officer, and it's Chief Scientific Officer. The President's employment agreement has a term of two years and will be automatically extended for additional one-year periods unless the Company notifies the President at least 180 days prior to the then current expiration date that it intends to not extend the employment agreement. The other two employment agreements provide for a base salary of \$350,000 per year for the President, \$290,000 per year for the Chief Medical Officer and \$315,000 per year for the Chief Scientific Officer. Each employee is also eligible for an annual discretionary bonus based on achievement of financial, clinical development and business milestones established by the Board of Directors, with the President eligible for a bonus of up to 50% of his base salary, and the Chief Medical Officer will also be eligible for a retention bonus payable after three months of employment in the amount of \$150,000 and \$100,000, respectively.

### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

#### Note 9 - Legal Proceedings:

In June 2012, the Company announced that its product iferanserin (VEN 309), failed to meet its end point at the completion of its Phase III clinical trial. In May 2013 two purported class action lawsuits alleging violations of the federal securities laws were filed in New York against the Company, two of its executive officers and the lead underwriter of its initial public offering. The lawsuits include allegations that, during the class period between December 17, 2010 and June 25, 2012, the Company and its executive officers and underwriter made various statements related to the Company's product, iferanserin (VEN 309), including but not limited to, the market for the product, the potential competitors, and the results of clinical trials, thereby inflating the price of our common stock. The complaints seek unspecified damages, interest, attorneys' fees, and other costs. On July 23, 2013, the Court consolidated the actions and appointed lead plaintiffs and lead counsel. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On November 22, 2013, the Company filed a motion to dismiss the consolidated amended complaint (the "Motion to Dismiss").

On May 5, 2014, the Court granted the Motion to Dismiss and dismissed the class action with prejudice.

On May 19, 2014, lead plaintiffs filed a Motion for Reconsideration of the Court's order dismissing the class action with prejudice (the "Motion for Reconsideration"). On July 2, 2014, the Court entered an order denying the Motion for Reconsideration. Lead plaintiffs had until August 2, 2014 to file notice of an appeal, but no appeal was filed.

#### Note 10 – Subsequent Events:

On October 6, 2014, the Company sold to various institutional investors an aggregate of 1,959,000 shares of common stock in a registered direct offering. The purchase price paid by the investors was \$8.04 per share and an aggregate of approximately \$14,900,000 in net proceeds were received. In connection with the offering, the Company entered into a placement agent agreement with William Blair & Company, L.L.C., who acted as sole placement agent in the offering, and pursuant to which the Company paid a placement agent fee equal to 5.0% of the gross proceeds of the offering.

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

The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2013, and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2013 filed on March 31, 2014. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to risks and uncertainties, including those set forth under "Part I. Item 1. Business - Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013, and elsewhere in this report, that could cause actual results to differ materially from historical results or anticipated results.

#### Overview

We are a biopharmaceutical company committed to applying our scientific knowledge in the field of infectious diseases to transform lives by discovering treatments for patients with Hepatitis B virus, or HBV, and clostridium difficile, or CDAD. On July 11, 2014, we merged with Assembly Pharmaceuticals Inc. (the "Assembly Merger"). In connection with the Assembly Merger, on July 11, 2014, we changed our name from Ventrus Biosciences, Inc. to Assembly Biosciences, Inc.

The target of our lead program is a clinical cure for HBV. Assembly Pharmaceuticals, Inc. has discovered a series of new compounds, known as core protein allosteric modulators, or CpAMs, that are capable of targeting and altering certain key proteins of HBV. These core proteins are involved in several steps of the HBV lifecycle and are essential for HBV's continued regeneration and survival. Modulation of these core proteins with Assembly's CpAMs has demonstrated preclinical proof of principle: multiple cell models have shown that CpAMs can selectively reduce the production of viral antigens—viral proteins responsible for common symptoms related to HBV—as well as reduce viral load—infectious viral particles circulating in the bloodstream.

Our second lead program, VEN 310, is based on a novel coating and encapsulation technology that allows for targeted delivery of complex agents to select regions of the gastrointestinal, or GI, tract. This delivery platform aims to deliver several types of beneficial specific bacteria to the gastrointestinal, or GI, tract. The technology builds upon experience reported in the literature of treating CDAD with fecal material transplant, or FMT, and seeks a path for potentially curative therapy using a targeted and specific microbiome therapy in an oral capsule.

Since our inception, we have had no revenue from product sales, and have funded our operations principally through debt financings prior to our initial public offering in 2010 and through equity financings since then. Our operations to date have been primarily limited to organizing and staffing our company, licensing our product candidates, developing clinical trials for our product candidates, establishing manufacturing for our product candidates, maintaining and improving our patent portfolio and raising capital. We have generated significant losses to date, and we expect to continue to generate losses as we continue to develop our product candidates. As of September 30, 2014, we had an accumulated deficit of \$129,282,721. Because we do not generate revenue from any of our product candidates, our losses will continue as we seek regulatory approval and commercialization of our product candidates. As a result, our operating losses are likely to be substantial over the next several years as we continue the development of our product candidates and thereafter if none is approved or successfully launched. We are unable to predict the extent of any future losses or when we will become profitable, if at all.

We believe that our existing cash will be sufficient to fund our projected operating requirements for at least the next twelve months.

Our operations are subject to other certain risks and uncertainties, including but not limited to: uncertainty of product candidate development; uncertainty of regulatory approval; unpredictability of the size of the markets for, and market acceptance of, any of our products; our anticipated capital expenditures, our estimates regarding our capital requirements; our ability to retain and hire necessary employees and to staff our operations appropriately; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. Any significant delays in the development or marketing of products could have material adverse effect on our business and financial results.

#### **Results of Operations**

#### Comparison of the Three Months Ended September 30, 2014 and September 30, 2013

#### Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was \$1,745,510 for the three months ended September 30, 2014, a decrease of \$1,855,083 or 51.52%, from \$3,600,593 for the same period in 2013. The reason for the decrease was due to the clinical trial for VEN 307 ending, offset by \$1,073,576 in research expenses for our HBV program.

Stock-based compensation was \$1,926,473 for the three months ended September 30, 2014, an increase of \$1,773,747 or 1,161.39%, from \$152,726 for the same period in 2013. The increase in compensation expense is primarily due to the granting of, and immediate vesting of a portion of stock options in July 2014.

#### General and Administrative Expense

General and administrative expense consists primarily of salaries, consulting fees and other related costs, professional fees for legal services and accounting services, insurance and travel expenses, as well as the stock based compensation expense associated with the grants of options to our employees, consultants and directors.

General and administrative expense, excluding stock-based compensation expense, was \$1,875,408 for the three months ended September 30, 2014, an increase of \$992,916 or 112.51% from \$882,492 for the three months ended September 30, 2013. The reason for the increase was mostly due to legal, accounting and other expenses for the merger with Assembly Pharmaceuticals.

Stock-based compensation expense was \$5,508,049 for the three months ended September 30, 2014, an increase of \$5,210,852 or 1,753.33%, from \$297,197 for the same period in 2013. The increase in compensation expense is primarily due to the granting of, and immediate vesting of a portion of stock options in July 2014.

#### Interest Income and Expense

Interest income was \$35,182 for the three months ended September 30, 2014 compared to \$51,266 for the same period in 2013 due to lower cash balances.

#### Comparison of the Nine Months Ended September 30, 2014 and September 30, 2013

#### Research and Development Expense

Research and development expense, excluding stock-based compensation expense, was \$5,740,868 for the nine months ended September 30, 2014, a decrease of \$3,629,173 or 38.73%, from \$9,370,041 for the same period in 2013. The reason for the decrease was a combination of the VEN 307 trial ending offset by \$1,073,576 in research expenses for our HBV program.

Stock-based compensation was \$2,000,449 for the nine months ended September 30, 2014, an increase of \$1,499,619 or 299.43%, from \$500,830 for the same period in 2013. The increase in compensation expense is primarily due to the granting of, and immediate vesting of a portion of, stock options in July 2014.

#### General and Administrative Expense

General and administrative expense, excluding stock-based compensation expense, was \$3,928,833 for the nine months ended September 30, 2014, an increase of \$1,239,828 or 46.11% from \$2,689,005 for the nine months ended September 30, 2013. The reason for the increase was mostly due to legal, accounting and other expenses for the merger with Assembly Pharmaceuticals.

Stock-based compensation expense was \$6,001,585 for the nine months ended September 30, 2014, an increase of \$5,050,727 or 531.18%, from \$950,858 for the same period in 2013. The increase in compensation expense is primarily due to the granting of, and immediate vesting of a portion of stock options in July 2014.

Interest income was \$112,287 for the nine months ended September 30, 2014 compared to \$154,009 for the same period in 2013, due to lower cash balances.

#### Liquidity and Capital Resources

#### Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any FDA-approved products to generate product sales revenue, we have not been profitable and have generated operating losses since we were incorporated in October 2005. We have funded our operations through September 30, 2014, principally with convertible debt and equity financing, raising an aggregate of approximately \$108.5 million in net proceeds from public offerings and private placements from inception to September 30, 2014.

Further, under a shelf registration statement filed with the Securities and Exchange Commission, or SEC, we raised approximately \$1.8 million in net proceeds under our at-the-market equity sales program in January 2014. In October 2014, we sold an aggregate of 1,959,000 shares of common stock under the shelf, resulting in net proceeds of approximately \$14,900,000. We do not anticipate selling any more shares under this shelf registration statement.

#### Net Cash Used in Operating Activities

Net cash used in operating activities was \$11,380,582 for the nine months ended September 30, 2014 and funded our research and development program and our general and administrative expenses.

#### Net Cash Used in Investing Activities

Net cash provided by investing activities was \$488,837 for the nine months ended September 30, 2014 principally cash acquired in the Assembly Merger.

#### Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$1,763,104 for the nine months ended September 30, 2014, and was from the sale of shares of our common stock pursuant to the at-the-market common equity sales program.

#### Funding Requirements

We expect to incur losses for at least the next several years as we develop our product pipeline. We expect to incur increasing research and development expenses as we begin preclinical and clinical activities on both platform technologies. We expect that our general and administrative expenses will also increase as we add infrastructure related to the merger with Assembly Pharmaceuticals. Our future capital requirements will depend on a number of factors, including the timing and outcome of preclinical activities, clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the acquisition of licenses to new products or compounds, the status of competitive products and the availability of financing.

Based on our cash position at September 30, 2014, (and after giving effect to approximately \$14,900,000 in net proceeds raised in our October 2014 common stock financing), and our analysis of our future development costs, we believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2016. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect, which would cause us to require additional capital earlier. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated preclinical and clinical activities. We will need to raise additional funds to continue and finalize the development of our product candidates.



We may need to finance our future cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements, or a bank credit facility or other financing vehicle if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate, and we may decide to raise additional funds even before we need them if the conditions for raising capital are favorable. We do not currently have any commitments for future external funding. The sale of additional equity or debt securities, if convertible, could result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations.

Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we need additional capital and adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable.

#### **Item 4. Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain a system of disclosure controls and procedures, as defined in Exchange Act Rule 13a-15(e), which is designed to provide reasonable assurance that information, which is required to be disclosed in our reports filed pursuant to the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), is accumulated and communicated to management in a timely manner. At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15(b). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective.

#### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting in the third quarter of 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



#### **PART II - OTHER INFORMATION**

#### **Item 1. Legal Proceedings**

On May 9 and May 21, 2013, respectively, two purported class action lawsuits were filed in the U.S. District Court for the Southern District of New York against us, two of our executive officers and the lead underwriter of our initial public offering: <u>Ted Davison, William Gould and Ray Lenci, Individually and on Behalf of All Others Similarly Situated</u>, <u>Plaintiffs v. Ventrus Biosciences</u>, <u>Inc.</u>, <u>et al</u>, 13CIV 3119; and <u>Michael Bartley</u>, <u>Individually and on Behalf of All Others Similarly Situated</u>, <u>Plaintiffs v. Ventrus Biosciences</u>, <u>Inc.</u>, <u>et al</u>, 13CIV 3429.

The complaints have been brought as purported stockholder class actions, and, in general, include allegations that, during the class period between December 17, 2010 and June 25, 2012, we and our two executive officers violated Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder, and our two executive officers and the lead underwriter of our initial public offering violated Section 20(a) of the Exchange Act in making various statements related to our product, iferanserin (VEN 309), a topical treatment for symptomatic hemorrhoids, including but not limited to, the market for the product, the potential competitors, and the results of clinical trials, thereby inflating the price of our common stock. The complaints seek unspecified damages, interest, attorneys' fees, and other costs.

On July 8, 2013, three prospective lead plaintiffs filed motions to consolidate, appoint a lead plaintiff, and appoint lead counsel (the "Motions to Consolidate"). The Court took the Motions to Consolidate under submission on July 17, 2013. On July 23, 2013, the Court consolidated the actions and appointed lead plaintiffs and lead counsel. On September 16, 2013, lead plaintiffs filed a consolidated amended complaint. On November 22, 2013, we filed a motion to dismiss the consolidated amended complaint (the "Motion to Dismiss").

On May 5, 2014, the Court entered an order granting the Motion to Dismiss and dismissed the class action with prejudice. On May 19, 2014, lead plaintiffs filed a Motion for Reconsideration of the Court's order dismissing the class action with prejudice (the "Motion for Reconsideration"). On July 2, 2014, the Court entered an order denying the Motion for Reconsideration. Lead plaintiffs had until August 2, 2014 to file notice of an appeal, but no appeal was filed.

#### Item 1A. Risk Factors

Except as set forth below, there have been no material changes to the discussion of risk factors included in our most recent Annual Report on Form 10-K and our most recent quarterly report on Form 10-Q.

#### We are dependent on a license relationship for each of our HBV therapy and VEN 310.

Our license agreement with Indiana University Research and Technology Corporation, or IURTC, from whom we have licensed our HBV therapy, requires us to make milestone payments based upon the successful accomplishment of clinical and regulatory milestones related to our HBV therapy. The total amount of all potential future milestone payments at June 30, 2014 is \$825,000. We also are obligated to pay IURTC royalty payments based on net sales of the licensed technology, which increase if we sublicense our rights to a non-affiliate third party. We are also obligated to pay diligence maintenance fees (starting at \$25,000 in 2014 and rising to \$100,000 in the year following first commercial sale of licensed product) each year to the extent that the royalty, sublicensing, and milestone payments to IURTC are less than the diligence maintenance fee for that year. Our license with Therabiome, LLC, from whom we have licensed VEN 310, also requires us to pay regulatory and clinical milestones as well as royalty payments to Therabiome. If we breach any of these obligations, we could lose our rights to VEN 310. If we fail to comply with similar obligations to any other licensor, it would have the right to terminate the license, in which event we would not be able to commercialize drug candidates or technologies that were covered by the license. Also, the milestone and other payments associated with licenses will make it less profitable for us to develop our drug candidates than if we owned the technology ourselves.

### We depend on our collaboration with Adam Zlotnick, the scientific founder of our HBV therapy. If that collaboration is not maintained, we may not be able to capitalize on the market potential of our HBV therapy.

Dr. Adam Zlotnick is the founder of our HBV therapy. We have entered into a three-year consulting agreement with Dr. Zlotnick pursuant to which he serves as the Chairman of our Scientific Advisory Board and provides consulting services as we request. Dr. Zlotnick could refuse to extend the agreement after its three-year term expires or we could terminate the consulting agreement for cause or no cause. Although Dr. Zlotnick assigned to us any rights to intellectual property related to our HBV therapy that arise during the term of the consulting agreement, and while the consulting agreement contains a non-compete during the term of the agreement, the loss of Dr. Zlotnick's services could materially impair our ability to further the development of our HBV therapy.

#### Unforeseen safety issues could hinder the development of our product candidates and their adoption, if approved.

Safety issues could arise during development of our product candidates, which might delay testing or prevent further development entirely. We have not yet tested our HBV therapy or VEN 310 and safety issues could arise during that planned testing or testing of any other product candidates. If a product is approved, any limitation on use that might be necessary could hinder its adoption in the marketplace. In addition, if any product is approved, it could be used against any instructions that we publish that limit its use, which could subject us to litigation.

# We lack suitable facilities for certain preclinical and clinical testing and expect to rely on third parties to conduct some of our research and preclinical testing and our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such research, testing or trials.

We do not have sufficient facilities to conduct all of our anticipated preclinical and clinical testing. As a result, we expect to contract with third parties to conduct most or all preclinical and clinical testing required for regulatory approval for our product candidates. We currently plan to outsource all clinical testing to third parties and are reliant on the services of these third parties to conduct studies on our behalf. If we are unable to continue with or retain third parties for these purposes on acceptable terms, we may be unable to successfully develop our product candidates. In addition, any failures by third parties to adequately perform their responsibilities may delay the submission of our product candidates for regulatory approval, which would impair our financial condition and business prospects.

Our reliance on these third parties for research and development activities also reduces our control over these activities but will not relieve us of our responsibilities. For example, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific requirements and standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. In addition, these third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical, nonclinical and preclinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our research, preclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. As a result, our results of operations and business prospects would be harmed, our costs could increase and our ability to generate revenues could be delayed.

#### Developments by competitors might render our product candidates or technologies obsolete or non-competitive.

The pharmaceutical and biotechnology industries are intensely competitive. In addition, the clinical and commercial landscape for HBV and CDAD is rapidly changing; we expect new data from commercial and clinical-stage products to continue to emerge. We will compete with organizations that have existing treatments and that are or will be developing treatments for the indications that our product candidates target. If our competitors develop effective treatments for HBV, CDAD or any other indication or field we might pursue, and successfully commercialize those treatments, our business and prospects might be materially harmed, due to intense competition in these markets.

### If we lose key management or scientific personnel, cannot recruit qualified employees, directors, officers, or other significant personnel or experience increases in our compensation costs, our business might materially suffer.

We are highly dependent on the services of our Chairman and Chief Executive Officer, Dr. Russell H. Ellison, our President and Chief Operating Officer, Derek Small, our Chief Medical Officer and Vice President of Research and Development, Dr. Uri Lopatin, our Chief Scientific Officer, Dr. Lee D. Arnold, and our Chief Financial Officer, David J. Barrett. Our employment agreements with Dr. Ellison, Mr. Small, Dr. Lopatin, Dr. Arnold and Mr. Barrett do not ensure their retention. This is also true for our other management team members, both present and future.

Furthermore, our future success also depends, in part, on our ability to identify, hire, and retain additional management team members as our operations grow. We expect to experience intense competition for qualified personnel and might be unable to attract and retain the personnel necessary for the development of our business. Finally, we do not currently maintain, nor do we intend to obtain in the future, "key man" life insurance that would compensate us in the event of the death or disability of any of the members of our management team.

#### If we cannot enforce non-compete and confidentiality provisions applicable to our employees and consultants, our business might materially suffer.

We include a non-compete provision in any employment agreement we enter into with an employee, including those for Messrs. Small and Barrett and Drs. Ellison and Arnold, that runs during the term of the agreement and for a period of time after termination, depending on the individual.

We include a confidentiality provision in any employment or consulting agreement we enter into with an employee or a consultant. The confidentiality provision runs during the term of the agreement and thereafter without limit.

For future employees with whom we do not enter into an employment agreement, we will enter into a confidentiality agreement with the same provisions described above.

To be able to enforce these non-compete and confidentiality provisions we would need to know of any breach and have sufficient funds to enforce the provisions. We cannot assure you that we would know of or be able to afford enforcement of any breach. In addition, such provisions are subject to state law and interpretation by courts, which could limit the scope and duration of these provisions. Any limitation on or non-enforcement of these non-compete and confidentiality provisions could have an adverse effect on our business.

#### If we are unable to hire additional qualified personnel, our ability to grow our business might be harmed.

At October 31, 2014, we had 18 employees, 10 consultants and multiple contract research organizations with whom we have contracted. We will need to hire or contract with additional qualified personnel with expertise in clinical research and testing, government regulation, formulation and manufacturing and sales and marketing to commercialize our HBV therapy and VEN 310 or any other product we may seek to develop. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for these individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

#### Our business depends on protecting our intellectual property.

If we and our licensors IURTC and Therabiome do not obtain protection for our respective intellectual property rights, our competitors might be able to take advantage of our research and development efforts to develop competing drugs. Our success, competitive position and future revenues, if any, depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade

secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and medicines that are important to our business. To date, although our licensors have filed patent applications, we do not own or have any rights to any issued patents that cover any of our product candidates, and we cannot be certain that we will secure any rights to any issued patents with claims that cover any of our proprietary medicines and technologies. The patent prosecution process is expensive and time-consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent process also is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our products by obtaining and defending patents. These risks and uncertainties include the following:

- Any patent rights, if obtained, might be challenged, invalidated, or circumvented, or otherwise might not provide any competitive advantage;
- Our competitors, many of which have substantially greater resources than we do and many of which might make significant investments in competing technologies, might seek, or might already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products either in the U.S. or in international markets;
- As a matter of public policy regarding worldwide health concerns, there might be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the U.S. for disease treatments that prove successful; and
- Countries other than the U.S. might have patent laws that provide less protection than those governing U.S. courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

In addition, the U.S. Patent and Trademark Office and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated.

Patent and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections, if obtained, will prove inadequate. Our business and prospects will be harmed if we fail to obtain these protections or they prove insufficient.

We might be involved from time to time in litigation to determine the enforceability, scope and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management's attention from our operations.

### We rely on trade secret protections through confidentiality agreements with our employees, customers and other parties, and the breach of these agreements could adversely affect our business and prospects.

We rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality, invention, and non-disclosure agreements with our employees, scientific advisors, consultants, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

### Item 6. Exhibits

Exhibit Number	Description of Document	Registrant's Form	Dated	Exhibit Number	Filed Herewith
10.29*	Exclusive License Agreement with Indiana University Research and Technology				Х
	Corporation				
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-				Х
	Oxley Act of 2002.				
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-				Х
	Oxley Act of 2002.				
32.1	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-				Х
	Oxley Act of 2002.				
32.2	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-				Х
	Oxley Act of 2002.				
101	Financials in XBRL format.				Х

\*Confidential treatment has been requested with respect to portions of this exhibit. Those portions have been omitted and filed separately with the

SEC.

### SIGNATURES

In accordance with the requirements of the Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

		Asse	Assembly Biosciences, Inc.		
Date: November 17, 2014		By:	/s/ Russell H. Ellison Russell H. Ellison Chief Executive Officer		
Date: November 17, 2014		By:	/s/ David J. Barrett David J. Barrett Chief Financial Officer		
	27				

Portions of this exhibit marked [\*] are requested to be treated confidentially.

EXCLUSIVE LICENSE AGREEMENT OF SEPTEMBER 3, 2013

between

#### INDIANA UNIVERSITY RESEARCH AND TECHNOLOGY CORPORATION

and

#### ASSEMBLY PHARMACEUTICALS, INC.

#### **IURTC Agreement Number ASS-0313-BB**

Introduction: This exclusive license agreement (the "Agreement") is made and entered into as of September 3, 2013 (the "Effective Date") by and between:

The Indiana University Research and Technology Corporation ("IURTC"), a non-profit corporation organized under the laws of the state of Indiana, having its principal offices at 351 West 10<sup>th</sup> Street, Indianapolis, Indiana 46202, and

Assembly Pharmaceuticals, Inc. ("Assembly"), a company organized under the laws of the state of Delaware, having its principal offices at 615 S. Clifton Ave., Bloomington, IN, 47401.

1 **Background:** Certain Patent Rights (as defined below) have been invented by Adam Zlotnick, Stella Aniagyei, Lichun Li, Michael S. VanNieuwenhze, Willam W. Turner at Indiana University , M.G. Finn at the Scripps Research Institute, Daniel D. Loeb at the University of Wisconsin (each of Zlotnick, Aniagyei, Li, VanNieuwenhze, Turner, Finn and Loeb, collectively, the "Inventors"), and Massimo Levrero at Sapienza University.

Under an inter-institutional agreement between IURTC and the the Scripps Research Institute; through a memorandum of understanding with Indiana University (Scripps and Indiana University collectively the "Institutions"); and by a direct assignment of Daniel D. Loeb to IURTC; IURTC has the sole right to grant licenses to IURTC's and the Institutions' patent rights. IURTC does not have the right to grant licenses to any ownership rights of Massimo Levrero or Sapienza University, and such ownership rights are not subject to this Agreement.

IURTC wishes to allow these Patent Rights to be used to further scientific research, for new product development, and for other applications in the public interest, and it is willing to grant a license for such uses. Assembly represents to IURTC that it has the necessary product development, manufacturing, and marketing capabilities to commercialize products based on such Patent Rights. Assembly desires to obtain a license to commercialize these intellectual property rights upon the terms and conditions set forth in this Agreement. In consideration of these premises and the mutual promises contained herein, the Parties further agree as follows:

- 2 **Definitions:** For the purposes of this Agreement, the following words and phrases have the meanings assigned to them below.
- 2.1 <u>Affiliate</u>: Any person or entity that, directly or indirectly, owns or controls Assembly or that is owned or controlled by or under common ownership or control with Assembly. Own(s) or control(s) means:
  - 2.1.1 Direct or indirect ownership of at least 50% of the outstanding voting securities of a corporation;
  - 2.1.2 The right to receive at least 50% of the earnings of the person, corporation, or other entity in question; or

- 2.1.3 The right to control the business decisions of the person, corporation, or other entity in question.
- 2.2 <u>Development Plan</u>: Assembly's good faith, bona fide plan for the development, manufacture, promotion, importation, use, sale and/or marketing of Licensed Products. The Development Plan will include, at a minimum:
  - 2.2.1 A definition and/or specification of each Licensed Product planned for development;
  - 2.2.2 Tasks to be performed by Assembly, its contractors and/or Sublicensees to develop each Licensed Product to the point of commercialization, including estimated time schedules for specific tasks;
  - 2.2.3 Tasks to be performed to achieve any regulatory approval or other certification of each Licensed Product, including estimated time schedules for each; and
  - 2.2.4 Identification of the primary country(ies) in which Assembly plans to sell each Licensed Product and a good faith estimate of time of First Commercial Sale in the primary country(ies).
- 2.3 <u>Field</u>: Diagnostics and therapeutics.
- 2.4 <u>First Commercial Sale</u>: The earliest date of Sale of a Licensed Product by Assembly or any of its Sublicensees. The transfer of Licensed Products by Assembly or its Sublicensees strictly for their own laboratory and clinical research and development purposes or beta-testing does not constitute a First Commercial Sale for the purposes of this Agreement, provided that Assembly or its Sublicensees receive no payment or other compensation or value for such Licensed Product in excess of the fully burdened (i.e., direct and indirect) costs of producing and transporting such materials.
- 2.5 <u>Licensed Product</u>: Any product: (i) the making, using or selling of which, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims (without giving effect to any safe harbor from infringement under 35 U.S.C. 271 (e)(1)); or (ii) that is made by, uses, or is used by a process that, absent the license granted hereunder, would infringe one or more pending or issued Valid Claims.
- 2.6 <u>Net Sales</u>: The fair market cash value of all value, compensation, and payments received from the Sale of Licensed Products, less the following:
  - 2.6.1 Trade, quantity, and cash rebates on Licensed Products actually provided to third parties;
  - 2.6.2 Credits, allowances, or refunds, not to exceed the original invoice amount, for actual claims, damaged goods, rejections, or returns of Licensed Products; and

2.6.3 Excise, sale, use, value added, or other taxes, other than income taxes, that are included in the amounts received and that are paid by Assembly or Sublicensees for Licensed Products.

In the event that a Licensed Product is bundled or integrated with one or more other products (such Licensed Product together with such other product(s), a "Bundled Product"), Net Sales will be calculated on the basis of the total invoice price of the Bundled Product multiplied by a fraction, the numerator of which will be the list price of the Licensed Product and the denominator of which will be an amount equal to the aggregate of all list prices of the Licensed Product and all other products in the applicable Bundled Product. In the event that there is Bundled Product and the list price of the Licensed Product and each other product in the applicable Bundled Product cannot be determined, then (a) the parties will negotiate in good faith to agree in writing on the relative value of the Licensed Product and each other product, which determination will be based upon sales prices for comparable products or processes, and (b) such relative value(s) will be used in calculating Net Sales. The deductions set forth in clauses 2.6.1 through 2.6.3 will be applied to the total invoice price for the applicable Bundled Product prior to calculating Net Sales of the Licensed Product.

- 2.7 <u>Party</u>: Individually, IURTC or Assembly. Collectively, IURTC and Assembly may be referred to as the "Parties."
- 2.8 Patent Rights:
  - 2.8.1 The patent applications (including provisionals) filed or to be filed as listed on Exhibit A;
  - 2.8.2 All U.S. patent applications directly or indirectly claiming priority to the above-referenced patents or applications, including divisionals, continuations, and claims in continuations-in-part applications that are entitled to the priority filing date of any of the above;
  - 2.8.3 Foreign equivalent applications;
  - 2.8.4 Patents issuing from the above applications;
  - 2.8.5 Reissues, re-examinations and extensions of the above, supplementary protection certificates and any patents issuing therefrom; and
  - 2.8.6 Any of the foregoing during reissue, re-examination, or post grant review proceedings.
- 2.9 The terms <u>Sale</u>, <u>Sold</u>, <u>Sell</u>: Any transaction in which a Licensed Product is exchanged or transferred for value, including without limitation sales, leases, licenses, rentals, provision of services through the use of Licensed Products, and other modes of distribution or transfer of a Licensed Product or its beneficial use. A Sale of a Licensed Product will be deemed to have been made when Assembly or its Sublicensee (or anyone acting on behalf of or for the benefit of Assembly or any of its Sublicensees) first invoices, ships, or receives value for a Licensed Product, whichever is earliest.

- 2.10 <u>Sublicensee</u>: A non-Affiliate third party to whom Assembly has granted a Sublicense pursuant to and in accordance with Article 3 of this Agreement. "Sublicense" is an arms-length agreement in which Assembly:
  - 2.10.1 Grants or sublicenses any of the rights granted hereunder;
  - 2.10.2 Agrees not to assert the Patent Rights or agrees not to sue, prevent, or seek a legal remedy for the practice of same; or
  - 2.10.3 Has agreed to do any of the foregoing, including but not limited to licenses, option agreements, right of first refusal agreements, standstill agreements, settlement agreements, co-development agreements, co-promotion agreements, joint venture agreements, or other agreements.
- 2.11 <u>Sublicensing Revenue</u>: The fair market cash value of any and all non-running royalty consideration received by Assembly from Sublicensees under or otherwise in connection with its Sublicenses, including without limitation license issue fees, option fees and other licensing fees, milestone payments, minimum annual royalties, equity or other payments of any kind whatsoever (but excluding running royalties paid for Net Sales of Licensed Products by Sublicensees), irrespective of whether such revenues are received in the form of cash, barter, credit, stock, warrants, release from debt, goods or services, licenses back, a premium on the sale of equity (i.e., payments for equity that exceed the pre-Sublicense value); provided, however, that Sublicensing Revenue will not include engineering charges, co-development payments or amounts received specifically in exchange for research and development, amounts received in exchange for equity, payments made for services and materials Assembly provides to Sublicensees, or other amounts received not relating to Licensed Products or Patent Rights.

"Supporting IP" means know-how, trade secrets, patents, and other forms of intellectual property and proprietary information owned, licensed to, or otherwise controlled by Assembly (other than through this Agreement), including without limitation technical data, clinical data, business information, follow-on inventions and improvements which are provided for use by a Sublicensee in the course of developing, testing, marketing, making, using, selling or otherwise exploiting Licensed Products.

2.12 <u>Term</u>: Commencing on the Effective Date and continuing until the expiration of the last to expire of the patents in the Patent Rights unless earlier terminated in accordance with this Agreement.

- 2.13 <u>Territory</u>: Anywhere in the world, except those countries to which export of technology or goods is prohibited by applicable United States export control laws or regulations.
- 2.14 <u>Valid Claim</u>: A claim of a pending Patent Rights patent application or of an issued and unexpired Patent Rights patent, in each case that has not lapsed or been held revoked, invalid or unenforceable by a court or other governmental agency of competent jurisdiction in a decision or order that is not subject to appeal, provided that if a pending patent application has not issued within five (5) years from receiving a first US office action or foreign equivalent, the claims of such patent application will no longer be considered Valid Claims hereunder.
- 3 **Grant:** Subject to the terms and conditions of this Agreement and in consideration of Assembly's satisfaction of its obligations hereunder, IURTC hereby grants to Assembly and Assembly hereby accepts, the following license during the Term in the Territory:
  - 3.1 An exclusive license to IURTC's and the Institutions' ownership rights in the Patent Rights, to make, have made, use, offer for sale, sell, and import Licensed Products in the Field.
  - 3.2 The rights licensed to Assembly hereunder, except for the right to grant Sublicenses, may be extended to Affiliates provided that each such Affiliate first agrees in a written agreement to be bound by the terms and conditions of this Agreement as Assembly is bound, and such agreement: (a) names IURTC as a third party beneficiary; (b) terminates upon termination of this Agreement; and (c) is not transferable. Any Affiliate that desires to exercise any of the rights granted hereunder will enter into such written agreement with Assembly prior to exercising such rights. Assembly will deliver to IURTC a copy of said agreement and any amendment thereto within thirty (30) days of each execution. Assembly agrees to be fully responsible for the performance of such Affiliates and liable for their compliance herewith.
  - 3.3 Assembly may grant Sublicenses to non-Affiliate third parties under this Agreement. Only Assembly, and not its Affiliates or Sublicensees, is permitted to grant Sublicenses.
    - 3.3.1 Any Sublicense granted by Assembly under this Agreement will be consistent with the terms and conditions of this Agreement and will:
      - 3.3.1.1 Contain the terms and conditions set forth in definition 2.6 and the definitions it references, and in paragraphs 3.4, 3.6, 3.7, 6.3, 8.5, 8.6, 9.7, 16.6, and 16.8, and in Article 7 modified only to indicate that Sublicensee is under the same obligations as Assembly;
      - 3.3.1.2 Contain the terms and conditions set forth in paragraph 6.2 and the definitions it references modified only to indicate that the Sublicensee is obligated to Assembly as Assembly is to IURTC; and

- 3.3.1.3 Contain the terms and conditions set forth in Articles 11, 12, and paragraph 7.5, modified only to indicate that the Sublicensee is obligated to IURTC and IU as Assembly is obligated to IURTC and IU hereunder.
- 3.3.2 If Assembly voluntarily enters bankruptcy or receivership, or if an involuntary bankruptcy action is filed against Assembly and not dismissed within ninety (90) days, then upon notice from IURTC, royalties based on Sublicensee's Net Sales and Sublicensing Revenue then or thereafter due to Assembly will become directly due and owing to IURTC for the account of Assembly. IURTC will remit to Assembly any amounts received that exceed the sum actually owed by Assembly to IURTC.
- 3.3.3 Within thirty (30) days of the effective date of any Sublicense, Assembly will provide IURTC a complete copy of the Sublicense and all exhibits thereto, along with Assembly's representation and warranty that no prior, contemporaneous, planned, or proposed contractual relationships between Assembly and Sublicensee contain consideration to Assembly reasonably attributable to the sublicensed rights. If the original Sublicense is written in a language other than English, the copy of the Sublicense and all exhibits thereto will be accompanied by a complete translation written in English. Assembly represents and warrants that such translation will be a true and accurate translation of the Sublicense and its exhibits.
- 3.3.4 Assembly agrees to be fully responsible for the performance of its Sublicensees hereunder. Any act or omission by a Sublicensee that would be a breach of this Agreement if imputed to Assembly will be deemed to be a breach by Assembly of this Agreement.
- 3.4 IURTC and the Institutions retain the right to practice under the Patent Rights for non-commercial educational and research purposes and permit other universities and non-profit research institutes to do the same for non-commercial educational and research purposes. Assembly may not in any way restrict the rights of IU, other universities or non-profit research institutions, or their faculty, staff, students, or employees from publishing the results of their research related to the Patent Rights.
- 3.5 This Agreement provides Assembly and Sublicensees no ownership rights of any kind in the Patent Rights. All ownership rights remain the property of the Institutions and/or IURTC.
- 3.6 In accordance with 35 U.S.C. §§ 200-212, 37 C.F.R. Part 401, and in the relevant government research contracts with the Institutions, the United States government retains certain rights to inventions arising from federally supported research or development. Under these laws and implementing regulations, the government may impose requirements on such inventions. To the extent applicable, such rights and requirements include without limitation (i) the grant of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the government any of the Patent Rights throughout the world, and (ii) the requirement that Licensed Products used or sold in the U.S. will be manufactured substantially in the U.S. The rights granted in this Agreement are expressly made subject to these laws and regulations as they may be amended from time to time. Assembly will be required to abide by all applicable laws and regulations. IURTC agrees to cooperate with Assembly in connection with attempting to secure any waiver of any obligations under 35 U.S.C. §204.

- 3.7 Assembly will mark all Licensed Products made or sold in the United States in accordance with 35 U.S.C. §287(a), and will mark all Licensed Products made or sold in other countries in accordance with the laws and regulation then applicable in each such country.
- 4 **Diligence:** Assembly agrees to use diligent efforts to develop, manufacture, promote and sell Licensed Products.
  - 4.1 Within ninety (90) days of the Effective Date, Assembly will provide IURTC with a Development Plan. Assembly will update the Development Plan to reflect the next year's plan and report progress for the past year against the Development Plan in writing to IURTC no later than January 31 of each subsequent year during the Term. The updates and reports will summarize in reasonable detail the progress achieved and any problems encountered in the development, evaluation, testing, manufacture, initial sale, and/or initial marketing of each Licensed Product. Upon reasonable request by IURTC, Assembly will consult with IURTC about tasks, schedules, and progress.
  - 4.2 In partial satisfaction of its obligations under this Article 4, Assembly will achieve the following commercial goals by the dates set forth below:
    - 4.2.1 Preparation of a preclinical development plan within three (3) months of the Effective Date;
    - 4.2.2 Preparation of a clinical development plan within six (6) months of the Effective Date;
    - 4.2.3 Negotiation of Series A financing of at least seven million dollars (\$7,000,000) within twenty-four (24) months of the Effective Date;

Assembly will provide IURTC with commercially reasonable evidence of Assembly's achievement of each of the above-defined commercial goals within thirty (30) days after the corresponding date.

## 5 **Financial Consideration:**

5.1 Assembly will pay to IURTC a royalty on Net Sales by Assembly and Sublicensees per calendar year as follows:

Net Sales	Royalty
Less than or equal to [*] dollars (\$[*])	0.5%
Greater than [*] dollars (\$[*]) and up to [*] dollars (\$[*])	[*]%
Greater than [*] dollars (\$[*]) and up to [*] dollars (\$[*])	[*]%
Greater than [*] dollars (\$[*])	1.75%

The royalty will apply to all Licensed Products made during the Term, though such products may be Sold after the Term. No multiple royalties will be payable because the Licensed Product, or the manufacture or use thereof, are or will be covered by more than one of the patent applications or patents in the Patent Rights. Royalties will be paid to IURTC within thirty (30) days of the end of each fiscal quarter in which the Net Sales occurred.

5.2 Beginning with the 2014 calendar year, Assembly will pay to IURTC an annual diligence maintenance fee according to the table below:

	di	iligence
calendar year	maint	tenance fee
2014	\$	25,000
2015	\$	50,000
2016 through the year in which First Commercial Sale occurs	\$	75,000
the year following First Commercial Sale and all subsequent years	\$	100,000

The diligence maintenance fee will be paid by Assembly to IURTC within thirty (30) days after the end of the calendar year for which it is due. For each calendar year, payments received by IURTC under paragraphs 5.1, 5.3, and 5.4 in such calendar year will be fully creditable against that year's diligence maintenance fee.

5.3 Assembly will pay to IURTC a percentage of Sublicensing Revenue according to the table below:

effective date of Sublicense	percentage of Sublicensing Revenue
Prior to beginning phase 1 clinical trials	[*]%
On or after beginning phase 1 clinical trials, but before beginning phase 2	
clinical trials	[*]%
On or after beginning phase 2 clinical trials	[*]%

## **IURTC Agreement Number ASS-0313-BB**

If a Sublicense is part of a transaction in which Assembly also conveys rights to Supporting IP, then Assembly will propose in good faith by written notice to IURTC a basis for allocation of the consideration received by Assembly for such transaction between the Patent Rights and the Supporting IP based on the relative value to be attributed to the Sublicense as part of the overall transaction. Such notice will describe in reasonable detail the rationale for such allocation. If IURTC in its good faith, reasonable discretion agrees with the proposal, the amount payable to IURTC under this Section 5.3 with respect to Sublicensing Revenue received in connection with such transaction will be determined by the following equation:

(x)(y)(z%) = A

where:

(x) is the relative value (expressed as a percentage) attributed to the Patent Rights;

(y) is the Sublicensing Revenue total received by Assembly;

(z) is the applicable rate as set forth in the table immediately above in this Section 5.3; and

A is the amount to be paid to IURTC

IURTC's percentage of Sublicensing Revenue will be paid by Assembly to IURTC within thirty (30) days of the end of each fiscal quarter in which Assembly received the Sublicensing Revenue.

- 5.4 Assembly will pay IURTC the following performance milestone payments:
  - 5.4.1 \$[\*] due within thirty (30) days of completion of the first phase 1 clinical trial;
  - 5.4.2 **\$**[\*] due within 30 days of completion of the first phase 2 clinical trial;
  - 5.4.3 **\$**[\*] due within 30 days of completion of the first phase 3 clinical trial;
  - 5.4.4 \$[\*] upon submission of the first application for regulatory approval of the first licensed product in a major market country (United States, Japan, France, Germany, United Kingdom, Italy); and
  - 5.4.5 \$[\*] upon the first regulatory approval of the first licensed product in a major market country (United States, Japan, France, Germany, United Kingdom, Italy).

Assembly will promptly notify IURTC of the achievement of a performance milestone. Should Assembly receive Sublicensing Revenue for a Sublicensee's achievement of a particular performance milestone listed above, Assembly will pay to IURTC the greater of the payment listed above or IURTC's percentage of Sublicensing Revenue under paragraph 5.3, it being understood that Assembly will not be required to pay both. Performance milestone payments will be paid by Assembly to IURTC within thirty (30) days of the end of each fiscal quarter in which the performance milestone is achieved.

- 5.5 If Assembly or an Affiliate or Sublicensee is required to make any payment (including, but not limited to, royalties or other license fees) to one or more third parties to obtain a patent license in the absence of which it could not legally make, import, use, sell, or offer for sale Licensed Product in any country, and Assembly provides IURTC with reasonably satisfactory evidence of such third-party payments, such third-party payments will be fully creditable against royalties owed to IURTC hereunder, provided that in no one year will the aggregate of all such expenses be credited against more than [\*] percent ([\*]%) of royalty payments that would otherwise be due to IURTC. Any greater amount of such expenses may be carried over and credited against royalties owed in future years, subject in every case to the [\*]% annual cap for that year.
- 5.6 Assembly will transfer to IURTC five percent (5%) of the outstanding equity in Assembly in existence as of the Effective Date. The transfer of such equity to IURTC will be made in accordance with the terms and conditions of an equity subscription agreement having commercially reasonable terms and conditions, the drafting of which will be the responsibility of Assembly, to be executed concurrently with this Agreement. The terms of such subscription agreement will be no less favorable to IURTC than the terms under which the most recent other common equity holder obtained equity. Said equity subscription agreement will contain provisions for, among others, (i) non-dilution of IURTC equity until the total Assembly paid-in capital exceeds five hundred thousand dollars (\$500,000), such equity to be subject to dilution thereafter at the same rate, and in the same manner as the other equity holders; (ii) the right of first refusal for IURTC or its affiliates to purchase IURTC's pro rata share of all (or any part) of any new securities that Assembly may from time-to-time issue after the Effective Date; and (iii) the right for IURTC to have its shares registered by "piggyback" on any public offering (other than Assembly's initial public offering) which may be made, subject only to "lock-up" provisions that are no more restrictive than those binding any other comparable pre-offering equity holder. Such equity transfer will in no event be subject to revocation, refund, or nullification in any instance and for any reason.

#### 6 **Payment and Reports:**

- 6.1 All dollar (\$) amounts referred to in this Agreement are expressed in United States dollars. All payments to IURTC will be made in U.S. dollars by check or electronic transfer payable to "Indiana University Research and Technology Corporation."
  - 6.1.1 Checks will be sent to:

Indiana University Research and Technology Corporation IU Innovation Center 351 W. 10<sup>th</sup> St. Indianapolis, IN 46202-4118

The IURTC Agreement Number ASS-0313-BB and purpose of the payment will be included with the check.

6.1.2 Wire transfer payments will be sent to:

For wire transfers from a U.S. bank: [\*]

For wire transfers from an international bank: [\*]

The IURTC Agreement Number ASS-0313-BB and purpose of the payment will be included with the wire transfer information. Assembly will add wire transfer fees to the payment.

- 6.1.3 Any amounts due in currency other than U.S. dollars will be converted to U.S. dollars at the conversion rate for the foreign currency as published in the Eastern edition of The Wall Street Journal as of the last business day in the U.S. of the applicable payment period.
- 6.2 Assembly will deliver to IURTC, with each payment made under paragraph 6.1, a written report describing the purpose of the payment and setting forth the calculation of the payment being made to IURTC, including the following:
  - 6.2.1 For payments under paragraph 5.1, calculations of payments due in connection with Net Sales by Assembly, by each Affiliate, and by each Sublicensee on a country-by-country basis: the number of Licensed Products Sold; gross receipts for Sales; deductions as described in paragraph 2.6, giving totals by each type; and Net Sales.
  - 6.2.2 For payments under paragraph 5.1 and 5.4, the serial numbers of the patent applications and patents in the Patent Rights that in Assembly's good-faith determination cover each Licensed Product.
  - 6.2.3 For payments under paragraph 5.2, a description and list of amounts credited against the diligence maintenance fee.
  - 6.2.4 For payments under paragraph 5.3, the name of the Sublicensee paying the Sublicensing Revenue to Assembly.
- 6.3 Assembly will maintain complete and accurate books of account and records that would enable an independent auditor to verify the amounts paid under this Agreement, and for otherwise verifying its performance hereunder. The books and records will be maintained for three (3) years following the quarter after submission of the reports required by this Article. Upon reasonable notice by IURTC, Assembly will give IURTC (or auditors or inspectors appointed by and representing IURTC) access to all books and records for Sales of Licensed Products to conduct, at IURTC's expense, an audit or review of those books and records. This access will be available no more than once every calendar year, during regular business hours, during the Term and for the three calendar years following the year in which termination or expiration occurs. Any underpayment will be promptly paid, with interest as set forth in paragraph 6.4, to IURTC. Any overpayment will be granted to Assembly as a credit against future payment. If the audit or review reports an underpayment by five percent (5%) or more for any fiscal quarter, Assembly will promptly reimburse IURTC for the costs and expenses of the accountants and auditors in connection with the review and audit.

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- 6.4 The past patenting costs in paragraph 9.3 are due within fifteen (15) days after the Effective Date, and if such payments are not timely received, this Agreement will be null, void, and without effect. All other payments not paid by Assembly to IURTC when due will accrue interest, from the due date until payment is made, at an annual rate equal to two percent (2%) above the prime rate published in the Eastern edition of The Wall Street Journal at the beginning of the period of arrearage (or the maximum allowed by law, if less than the amount specified herein).
- 6.5 Any taxes required to be withheld by Assembly from payments otherwise due under Article 5 in order to comply with the tax laws of the United States or any other country will be promptly paid by Assembly to the appropriate tax authorities, and Assembly will furnish IURTC with original tax receipts or other appropriate evidence issued by the appropriate tax authorities sufficient to enable IURTC to support a claim for income tax credit or refund in respect to any sum so withheld.

## 7 **Confidentiality:**

- 7.1 The terms and conditions of Articles 4 and 5 and information exchanged between the Parties under Articles 4, 6, and 9, as well as any information designated by a Party in any reasonable manner as confidential within a reasonable time after it is delivered to the receiving Party, are Confidential Information.
- 7.2 During the Term and for a period of three (3) years thereafter, the receiving Party agrees to maintain in secrecy and not disclose to any third party any Confidential Information received, and to use reasonable measures to ensure the confidentiality of such Confidential Information. Receiving Party will use the Confidential Information received solely as necessary to perform its obligations and exercise its rights in accordance with ther terms and conditions of this Agreement.
- 7.3 Confidential Information does not include information that:
  - 7.3.1 Is or becomes publicly known through no fault of the receiving Party;
  - 7.3.2 Was known to the receiving Party before disclosure by the disclosing Party as established by documentary evidence;
  - 7.3.3 Is identical subject matter originally and independently developed by the receiving Party's personnel without knowledge or use of or access to any disclosing Party's Confidential Information as established by documentary evidence; or

- 7.3.4 Was disclosed to the receiving Party without restriction by a third party having a right to make the disclosure.
- 7.4 Notwithstanding the other terms of this Article 7,
  - 7.4.1 Assembly may, to the extent necessary, use Confidential Information to secure governmental approval to clinically test or market a Licensed Product, to comply with a court order or governmental rule or regulation, or to show to a potential or actual sublicensee, contractor, investor, acquirer or professional adviser, subject to an appropriate confidentiality agreement (or in the case of professional advisers, ethical obligations). Assembly will, in any such use, take all reasonably available steps to maintain confidentiality of the disclosed information and to guard against any further disclosure.
  - 7.4.2 IURTC may report consideration received under this Agreement and Assembly's progress under Article 4, including providing the Development Plans and reports, to the Institutions and the Inventors.
- 7.5 Neither Party may use the name of the other for any commercial, advertisement, or promotional purpose without the prior written consent of the other. Assembly may not use the name of the Institutions for any commercial, advertisement, or promotional purpose without the prior written consent of the Institutions. However, each Party may state that Assembly licensed from IURTC one or more of the patent applications and/or patents in the Patent Rights and may further include (i) Institutions' Inventors' names, (ii) invention titles and summaries, (iii) Field, and (iv) type and extent of license. The foregoing shall not restrict either Party from making disclosures or statements as required by law or regulation.

#### 8 **Representations and Warranties:**

- 8.1 IURTC represents and warrants that:
  - 8.1.1 It is a corporation organized, existing, and in good standing under the laws of the state of Indiana;
  - 8.1.2 It has the authority to enter into this Agreement and that the person signing on its behalf has the authority to do so;
  - 8.1.3 To the best of its knowledge, it is the sole owner of the Patent Rights listed on <u>Exhibit A</u> that are identified as being an "IURTC solely owned Patent Right", and a co-owner of all other Patent Rights (in each case, subject to any rights retained by the United States government by operation of law) and it has the authority to grant the licenses set forth herein; and

- 8.1.4 To the best of its knowledge, as of the Effective Date of the Agreement, there are no actions, suits or claims pending against IURTC challenging IURTC's ownership or control of the Patent Rights licensed in this Agreement.
- 8.2 Assembly represents and warrants that:
  - 8.2.1 It is a company duly organized, existing, and in good standing under the laws of the state of Delaware;
  - 8.2.2 The execution, delivery and performance of this Agreement have been authorized by all necessary corporate action on the part of Assembly and that the person signing the Agreement on behalf of Assembly has the authority to do so;
  - 8.2.3 The making, exercising of any right, or performance of any obligation under this Agreement does not violate any separate agreement it has with a third party, and in so acting, Assembly will not breach the terms and conditions of this Agreement or fail to comply with applicable laws, regulations, and court orders;
  - 8.2.4 It is not a party to any agreement or arrangement that would prevent it from performing its duties and fulfilling its obligations to IURTC under this Agreement;
  - 8.2.5 It has and will maintain at the time specified in Article 12, the insurance coverage called for in Article 12;
  - 8.2.6 It will obtain any additional licenses from any third party needed to perform and fulfill its duties and obligations under this Agreement, including, but not limited to, the Development Plan; and
  - 8.2.7 There is no pending litigation and no threatened claims against it that could impair its ability or capacity to perform and fulfill its duties and obligations under this Agreement, including, but not limited to, the Development Plan.
- 8.3 EXCEPT AS PROVIDED IN PARAGRAPH 8.1 and 8.2, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES, AND EXPRESSLY DISCLAIM ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, STATUTORY, IMPLIED, OR OTHERWISE, INCLUDING:
  - 8.3.1 A warranty or representation as to the validity, scope, or efficacy of the Patent Rights;

- 8.3.2 A warranty or representation that the exercise of any rights granted in this Agreement does not or will not infringe patents, copyrights, trademarks, trade secrets or other proprietary rights of third parties;
- 8.3.3 A warranty or representation of operability or that development of a Licensed Product is possible;
- 8.3.4 An obligation to bring or prosecute actions or suits against third parties for infringement of the Patent Rights;
- 8.3.5 A grant, by implication, estoppel, or otherwise, of any licenses or rights under patents or other intellectual property rights of IURTC, the Institutions, or other persons, other than the rights expressly granted above to the Patent Rights;
- 8.3.6 Directly or indirectly operating or applying as a waiver of sovereign immunity by the state of Indiana; or
- 8.3.7 Imposing any obligation or any liability on any party contrary to the laws of the state of Indiana.
- 8.4 IURTC PROVIDES THE PATENT RIGHTS "AS IS." IURTC MAKES NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS OF THE PATENT RIGHTS OR ANY LICENSED PRODUCTS FOR ANY PURPOSE, OR THAT THE USE OF THE PATENT RIGHTS OR ANY LICENSED PRODUCT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS OF THIRD PARTIES. IURTC MAKES NO REPRESENTATION OR WARRANTY WITH RESPECT TO THE PERFORMANCE OF THE PATENT RIGHTS OR ANY LICENSED PRODUCT, INCLUDING THEIR SAFETY, EFFECTIVENESS, OR COMMERCIAL VIABILITY. IURTC will not be liable, including to Assembly, its affiliates, successors, assigns, contractors, independent contractors, or sublicensees, or to any third party regarding any claim arising from or relating to Assembly's use of the Patent Rights or from the manufacture, use, or importation of products (other than solely and exclusively resulting from any material breach of this Agreement or gross negligence or willful misconduct by IURTC); or for any claim for loss of profits or loss or interruption of business; or for indirect, special, exemplary, punitive, or consequential damages of any kind. The above limitations on liability apply even if advised of the possibility of such damages.
- 8.5 It is understood that IURTC and Assembly are subject to United States laws and regulation (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979) controlling the export of technical data, computer software, laboratory prototypes, and other commodities, and that such obligations hereunder are contingent upon compliance with applicable U.S. export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the U.S. Government and/or written assurances by Assembly that Assembly will not export data or commodities to certain foreign countries without prior approval of such agency. IURTC does not represent that a license is not required, or that, if required, such a license will be issued.

8.6 It is understood that IURTC and Assembly are subject to United States and foreign laws and regulations prohibiting bribery, including, but not limited to, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and that the obligations of IURTC and Assembly under this Agreement are contingent upon compliance with the U.S. Foreign Corrupt Practices Act. IURTC is not obligated to take any action that it believes in good faith may cause it to be in violation of the U.S. Foreign Corrupt Practices Act or other U.S. laws.

## 9 **Prosecution of Patent Rights:**

- 9.1 IURTC is the owner or co-owner of the Patent Rights and will have exclusive control of the preparation, filing, prosecution, issue, and maintenance of the Patent Rights. Maintenance includes but is not limited to post-issuance proceedings such as post-grant reviews, reissue proceedings, and re-examination proceedings. IURTC will select qualified patent counsel reasonably acceptable to Assembly to prepare, file, prosecute and maintain the Patent Rights. IURTC will keep Assembly fully informed of patent prosecution, will seek Assembly's comments and suggestions prior to taking material actions for the same, and will take all prosecution actions reasonably recommended by Assembly which would expand the scope of rights sought.
- 9.2 IURTC will authorize Assembly to communicate directly with IURTC's patent counsel. All information exchanged among IURTC's counsel, the Parties, and/or the Inventors regarding the preparation, filing, prosecution, issue, or maintenance of the Patent Rights will be deemed Confidential Information. In addition, the Parties acknowledge and agree that, with regard to such preparation, filing, prosecution, issue, and maintenance of the Patent Rights, the interests of the Parties as licensor and licensee are to obtain the strongest and broadest patent protection possible, and as such, are aligned and legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights, including without limitation, privilege under the common interest doctrine and similar or related doctrines.
- 9.3 Assembly will reimburse IURTC within fifteen (15) days after the Effective Date for expenses incurred prior to the Effective Date for preparing, filing, prosecuting, issuing, and maintaining the Patent Rights.
- 9.4 During the Term, Assembly will reimburse IURTC for all reasonable and documented costs and expenses incurred by IURTC in the preparation, filing, prosecution, issue, and maintenance of the Patent Rights within thirty (30) days of receipt of billing invoices for such costs and expenses. Notwithstanding the foregoing:
  - 9.4.1 IURTC may, at its sole discretion, require Assembly to pay patent counsel a retainer for filing fees prior to filing patent applications in foreign countries; and

- 9.4.2 Should Assembly become delinquent at any time for the reimbursement of patenting costs, IURTC may, at its sole discretion, require Assembly to pay patent counsel a retainer for future expenses.
- 9.5 IURTC will diligently prosecute and maintain the Patent Rights as long as Assembly timely satisfies its reimbursement obligations hereunder.
  - 9.5.1 IURTC will prepare, file, and prosecute additional applications within the Patent Rights as Assembly may reasonably request, in IURTC's name at Assembly's sole expense.
  - 9.5.2 IURTC may request written notice from Assembly of Assembly's intent to satisfy its reimbursement obligations for any particular fees or expenditures for any patent application or patent in the Patent Rights at least sixty (60) days in advance of the date on which such expenditure is to be made or such fee is due to be paid. Assembly will respond either by affirming its intent to satisfy its reimbursement obligations or by electing not to pay in accordance with paragraph 9.6. Should Assembly fail to respond to IURTC's request, IURTC may, at its sole discretion, (i) incur such fee or expenditure and Assembly will be obligated to reimburse same; or (ii) decline to incur such fee or expenditure even if this results in the abandonment of patent applications or patents in the Patent Rights.
- 9.6 If Assembly elects not to pay for any fees or expenditures for any Patent Rights, Assembly will give IURTC written notice of such election at least sixty (60) days in advance of the date on which such expenditure is to be made or such fee is due to be paid. Upon IURTC's receipt of such notice, the license granted to Assembly for those patent applications or patents in the Patent Rights will terminate, and IURTC will be free, at IURTC's sole discretion and without any further obligation to Assembly, to continue prosecution and maintenance for IURTC's sole use and benefit, or to abandon the patent applications or patents.
- 9.7 Assembly and IURTC agree that the Patent Rights will be extended by all means provided by law or regulation, including without limitation extensions provided under United States law at 35 U.S.C. §154(b) and 156. Assembly hereby agrees to provide IURTC with all necessary assistance in securing such extension, including without limitation, providing all information regarding applications for regulatory approval, approvals granted, and the timing of same. Assembly acknowledges that extension under 35 U.S.C. §156 must be applied for within sixty (60) days of the date that a Licensed Product receives permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use, and that Assembly's failure to promptly provide the necessary information or assistance to IURTC during such sixty day period will cause serious injury to IURTC, for which Assembly will be liable at law.

#### 10 Third Party Infringement:

- 10.1 The Parties will give prompt written notice to each other of any known or suspected infringement of the Patent Rights by a third party. Assembly at its sole expense has the right to attempt to abate any infringement of the Patent Rights in the Field. Assembly may initiate and prosecute actions against third parties for infringement and/or unfair trade practices, and if required by law, IURTC will permit any action to be brought in its name, including being joined as a party-plaintiff. Assembly will consult with IURTC prior to and in conjunction with all significant issues, will keep IURTC informed of all proceedings, and will provide copies to IURTC of all pleadings, legal analyses, and other papers related to such actions. IURTC will provide reasonable assistance to Assembly in prosecuting any such actions and will be compensated by Assembly for its reasonable out-of-pocket expenses, which IURTC will only be required to expend if Assembly has approved same for reimbursement. Absent IURTC's prior written consent, Assembly will not settle or compromise any claim or action in a manner that grants rights or concessions to a third party to the Patent Rights.
- 10.2 Any damages paid (including without limitation statutory damages, compensatory damages, lost profits damages, exemplary damages, increased damages, and awards of costs and attorney fees) will first be applied to reimbursement of Assembly's reasonable costs, expenses, and legal fees, including amounts Assembly has reimbursed to IURTC. Assembly will retain the remaining balance of such damages, subject to payment to IURTC of an amount based upon a reasonable approximation of the royalties and other amounts that Assembly would have paid to IURTC if Assembly had sold the infringing products rather than the infringer. Any special or punitive damages will be distributed [\*] percent ([\*]%) to Assembly and [\*] percent ([\*]%) to IURTC.
- 10.3 If Assembly fails or declines to take any action under paragraph 10.1 within sixty (60) days after learning of third party infringement or unfair trade practices, IURTC will have the right, but not the obligation, to take appropriate actions against any such third party at its sole expense and to retain all recovered damages. In such instances, Assembly will cooperate as requested by IURTC, and will be compensated by IURTC for its reasonable out-of-pocket expenses, which Assembly will only be required to expend if IURTC has approved same for reimbursement.
- 10.4 Assembly may offset a total of [\*] percent ([\*]%) of any expenses incurred under this Article 10 against any payments due to IURTC under Article 5, provided that in no event will such payments under Article 5, when aggregated with any other offsets and credits allowed under this Agreement, be reduced by more than [\*] percent ([\*]%) in any reporting period.

## 11 Indemnification:

- 11.1 Assembly will indemnify, defend, and hold harmless IURTC, the Institutions, their respective Board of Directors, trustees, employees, the Institutions's faculty, staff, employees, students, successors, assigns, independent contractors, and agents (collectively, "IURTC Indemnitees") from and against any and all judgments, liabilities, losses, or damages, (including all attorney fees and costs incurred by IURTC Indemnitees) (collectively, "Losses") in connection with any actions or claims brought by any third party arising out of, relating to, or incidental to the exercise of any rights or breach of any term or condition under this Agreement by Assembly or its Affiliates, successors or assigns, or Sublicensees (provided, however, that Assembly will have no obligation pursuant to the foregoing with respect to any Losses that result soley and exclusively from the gross negligence or willful misconduct of any IURTC Indemnitee), including but not limited to:
- \* [\*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

- 11.1.1 The use of any Patent Rights in the design, development, production, manufacture, sale or offer for sale, use, importation, lease, marketing or promotion of any Licensed Product;
- 11.1.2 Injury or death to any person, damage to property, or any injury to business, including, but not limited to, business interruption or damage to reputation, arising out of, relating to, or incidental to the use of the Patent Rights or a Licensed Product; and
- 11.1.3 Any third party claim that any use or licensing of the Patent Rights or development, provision, or use of Licensed Products violates or infringes a third party's intellectual property rights.
- 11.2 Assembly at its sole expense will defend third party claims. Assembly will have the right to conduct the defense of such actions. Assembly will consult with IURTC prior to and in conjunction with all significant issues, will keep IURTC informed of all proceedings, and will provide copies to IURTC of all pleadings, legal analyses, and other papers related to such actions. IURTC will provide reasonable assistance to Assembly in defending any such actions and IURTC Indemnitees may be represented by counsel of its choosing at its expense. Assembly will not settle or compromise any claim or action in a manner that imposes restrictions or obligations on IURTC Indemnitees or requires any financial payment or admission of liability by IURTC Indemnitees.
- 11.3 If Assembly fails to defend a claim or action for which it is required to provided indemnification under this Article 11 within twenty (20) days of learning of the same, in addition to and not in lieu of other rights and remedies, IURTC may assume the defense for the account of and at the risk of Assembly, and any resulting liability, including attorney fees, will be deemed conclusively to be a liability of Assembly. Assembly's failure or refusal to act is a material breach of this Agreement. If it is determined by a court of competent jurisdiction that such claim is not within Assembly's indemnification obligations under this Article 11 the foregoing will not apply, Assembly's failure or refusal to act will not be deemed a material breach, and any termination will be reversed.

#### 12 Insurance:

- 12.1 Assembly will at all times comply, through insurance, with all statutory workers' compensation and employers' liability requirements covering all employees with respect to activities undertaken in performance of this Agreement.
- 12.2 In addition to the foregoing, Assembly and Sublicensees will obtain and maintain commercial general liability insurance with a reputable and financially secure insurance carrier prior to making, using, importing, offering to sell, or selling any Licensed Product, or engaging in any other act involving any Licensed Product or the Patent Rights, if such act could possibly create risk of a claim against IURTC Indemnitees for personal injury or property damage.
  - 12.2.1 The insurance will identify IURTC as an additional insured and will provide that the carrier will notify IURTC in writing at least thirty (30) days prior to cancellation or material change in coverage.
  - 12.2.2 The insurance will include coverage for product liability with a minimum of two million dollars (\$2,000,000) per occurrence and five million dollars (\$5,000,000) annual aggregate, coverage for contractual liability, and all other coverages standard for such policies.
  - 12.2.3 Insurance policies purchased to comply with this Article will be kept in force for at least five (5) years after the last Sale of Licensed Product.
- 12.3 At IURTC's request, such request to be made no more than annually, Assembly will provide IURTC with a certificate of insurance and notices of subsequent renewals for its insurance and that of any Sublicensee.
- 12.4 The specified minimum coverages and other provisions of this Article 12 do not constitute a limitation on Assembly's obligation to indemnify the IURTC Indemnitees under this Agreement.

#### 13 **Termination:**

- 13.1 Assembly may terminate this Agreement with or without cause on ninety (90) days advance written notice to IURTC. The license rights granted in Article 3 will terminate and all rights granted will automatically revert to IURTC at the end of the 90-day period.
- 13.2 IURTC may terminate this Agreement on sixty (60) days advance written notice to Assembly upon Assembly's material breach of the Agreement. The termination becomes effective at the end of the 60-day period unless Assembly has fully cured the breach within that time. A material breach includes, but is not limited to, the following:
  - 13.2.1 Failure to timely pay any fee, royalty, or other payment required, including but not limited to those due under Article 5, paragraph 6.3, Article 9, or paragraph 10.2, and including any interest on late payments under paragraph 6.4;

- 13.2.2 Failure to timely provide reports or notices, including but not limited to those due under paragraphs 3.2, 3.3, 4.1, 6.2, or 14.1;
- 13.2.3 Failure to keep accurate and completed books and records under paragraph 6.3;
- 13.2.4 Failure to obtain, maintain, or timely report levels of insurance under Article 12;
- 13.2.5 Failure to include all required terms in sublicenses, or inclusion of any prohibited terms under paragraph 3.3; and
- 13.2.6 Failure to indemnify IURTC Indemnitees or properly inform or involve IURTC under Article 11.
- 13.3 Assembly further agrees that IURTC, at its sole discretion, may immediately terminate the Agreement by means of a written notice to Assembly in the event that Assembly makes an assignment for the benefit of its creditors, or in the event that Assembly voluntarily files for bankruptcy or in the event an involuntary bankruptcy action is filed against Assembly and not dismissed within ninety (90) days. Assembly will promptly inform IURTC of its intention to file a voluntary petition in bankruptcy or of another's communicated intention to file a voluntary petition in bankruptcy.
- 13.4 As of the date of termination of this Agreement by either Party for any reason pursuant to the terms herein, including expiration of the Term, all license rights granted to Assembly, including to all Affiliates, will terminate and all rights granted will automatically revert to IURTC. Assembly's obligations to pay fees, royalties, or other payments and patent expenses accruing prior to termination will survive termination.
- 13.5 Upon termination of this Agreement, Assembly will promptly notify its Sublicensees of such termination. Any rights previously granted by Assembly under any Sublicense hereunder will be automatically revoked thirty (30) days following the effective date of termination of this Agreement. However, Sublicensees have the right to enter into a written license agreement with IURTC before their Sublicense is revoked, through which such Sublicensee will become bound to IURTC on substantially the same terms and conditions (including financial terms) as it was bound to Assembly under the Sublicense, but only to the extent that each financial term is no less favorable to IURTC than those set forth in Article 5 and paragraphs 9.3 and 9.4, and provided that the Sublicense does not impose any obligations on IURTC in excess of those imposed under this Agreement. If any Sublicensee desires to enter into such a license agreement, it will be wholly the responsibility of that Sublicensee to notify IURTC of such desire within thirty (30) days after the effective date of termination of this Agreement. IURTC hereby agrees to enter into such a license agreement will automatically result in the termination of the Sublicense and all rights granted thereunder.

- 13.6 All representations, warranties, covenants, and agreements made herein that, by their express terms or by implication, are to be performed after the expiration or termination of this Agreement, or are prospective in nature, will survive such expiration and/or termination, as the case may be. This will include, but not be limited to, the provisions in Articles 5, 6, 7, 8, 11, 12, 13, 14, and 16.
- 13.7 Assembly will promptly notify IURTC of the termination of any agreement or grant to an Affiliate under paragraph 3.2 or to a Sublicensee under paragraph 3.3.

## 14 Assignment of the Agreement:

- 14.1 The Agreement, in whole or in part, will not be assigned by either Party to any third party without the written consent of the non-assigning Party. However, Assembly may assign the entire Agreement to a third party that acquires substantially all of Assembly's business, equity or assets through merger, sale, acquisition, or other similar transaction, provided that:
  - 14.1.1 Assembly is not in breach of the Agreement in any respect; and
  - 14.1.2 Assembly demonstrates to IURTC's satisfaction, not to be unreasonably withheld, that the successor has or is likely to acquire capital and manpower resources sufficient to fulfill the obligations it is assuming hereunder; and
  - 14.1.3 The successor agrees in writing (with a copy of such assent to IURTC within ten (10) days of the effective date of the assignment) to assume all obligations and liabilities, including this Agreement, of Assembly to IURTC.
- 14.2 The rights granted in this Agreement may not be encumbered, pledged, or hypothecated in any way by Assembly or any Sublicensee, including but not limited to secure any purchase, lease, or loan.
- **Notice:** Any required or permissive notice under this Agreement will be sufficient if in writing and delivered personally, by recognized national overnight courier, or by registered or certified mail, postage prepaid and return receipt requested, to the address below and will be deemed to have been given as of the date shown on the receipt if by certified or registered mail, or the day following dispatch if by overnight courier.

## If to IURTC:

Vice President Office of Technology Commercialization Attn: IURTC Agreement #ASS-0313-BB Indiana University Research and Technology Corporation 351 W. 10<sup>th</sup> Street Indianapolis, IN 46202

## If to Assembly:

Assembly Pharmaceuticals, Inc. Attn: Derek Small, Executive Chair 615 S. Clifton Ave. Bloomington, IN 47401

### 16 General Provisions:

- 16.1 This Agreement will be construed, interpreted, and applied according to the laws of the state of Indiana, without regard to its or any other jurisdiction's conflicts of laws provisions. Assembly agrees that all claims, disputes, or controversies arising under or relating to this agreement, including but not limited to those concerning the validity, construction, or scope of any of the Patent Rights will be subject to the exclusive jurisdiction and venue of the state or Federal District Court seated in Marion County, Indiana.
- 16.2 This Agreement is binding on the Parties and their respective successors and assigns and inures to the benefit of the Parties and their respective permitted successors and permitted assigns. No waiver of any breach of this Agreement will constitute a waiver of any other breach of the same or any other provision of the Agreement, and no waiver will be effective unless made in writing by the Party against whom the waiver is sought to be asserted. The delay or failure to assert a right or to insist upon compliance with any terms or condition of this Agreement will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition.
- 16.3 The Parties acknowledge that they have read this Agreement, including any Exhibits attached hereto, in its entirety and agree that this instrument comprises the entire agreement, contract, and understanding of the Parties on the subject matter of the Agreement. The Parties acknowledge that invoices, purchase orders, or other mechanisms for administering any payment or obligation set forth herein will not contain terms and conditions separate from, in addition to, and/or in conflict with the Agreement, and that any such terms, if present, will be void and without effect, and will not be enforceable by any Party. The initial drafting of the Agreement by IURTC was for the convenience of both Parties, that the Parties had opportunity to be advised by counsel of its choosing and as such both Parties agree the clauses will not be construed against IURTC as the drafter should such clause become in dispute.
- 16.4 This Agreement cannot be changed, modified, or amended except by a written instrument subscribed by authorized representatives of the respective Parties.
- 16.5 Neither Party is an agent or contractor of the other as a result of any transaction under this Agreement. Neither Party may in any way pledge the other Party's credit or incur any obligation on behalf of or bind the other Party.

- 16.6 The provisions of this Agreement are severable in that if any provision in the Agreement is finally determined by a court of competent jurisdiction to be invalid or unenforceable, such invalidity or non-enforceability will not in any way affect the validity or enforceability of the remaining provisions or the validity or enforceability of such provision in any jurisdiction where valid and enforceable. Any invalid or unenforceable provision will be reformed by the Parties to effectuate their intent as evidenced on the Effective Date.
- 16.7 If the performance of any obligation under this Agreement is prevented or impaired by acts of God or natural disaster, interference by civil or military authorities, war, riot, or governmental laws or regulations, a Party will be excused from performance so long as such cause continues to prevent or impair that Party's performance. The Party claiming such force majeure excuse will promptly notify the other Party of the existence of the cause and will at all times use diligent efforts to resume and complete performance.
- 16.8 Assembly agrees that in the event an Institution's faculty or staff member serves Assembly in the capacity of consultant, officer, employee, board member, advisor, or other designation, pursuant to contract or otherwise, such Institution's faculty or staff member is subject to compliance with Institution's conflict of interest and conflict of commitment policies, including the obligation to complete a disclosure therefor, will serve in his or her individual capacity, as an independent contractor, and not as an agent or representative of IURTC or Institutions, that IURTC or Institutions exercises no authority or control over such faculty or staff member while acting in such capacity, that IURTC or Institutions receives no benefit from such activity, and that IURTC or Institutions assume no liability or obligation in connection with any such work or service undertaken by such faculty or staff member. Assembly further agrees that any breach, error, or omission by an Institutions, and will not constitute a breach of this Agreement by IURTC.
- 16.9 This Agreement may be executed in counterparts, each of which will be deemed an original and all of which when taken together will be deemed one instrument.

## IURTC Agreement Number ASS-0313-BB

Witness: The Parties have caused this valid and binding agreement to be executed in duplicate by their duly qualified representatives as of the Effective Date.

Assembly:	IURTC:
Signature	Marie C. Kerbeshian, Ph.D
Name	Vice President Office of Technology Commercialization
Title	Date
Date	

## **Exhibit A. Patent Rights**

## **IURTC solely owned Patent Rights**

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**IURTC and Institution jointly owned Patent Rights** 

[\*]

IURTC and Levrero/Sapienza owned Patent Rights\*

[\*]

\*IURTC does not have the right to license any ownership rights that belong to Massimo Levrero or Sapienza, and such ownership rights are not subject to this Agreement.

#### CERTIFICATION

## I, Russell H. Ellison, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2014

By:

/s/ Russell H. Ellison Russell H. Ellison Chief Executive Officer I, David J. Barrett, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Assembly Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 17, 2014

By: /s/ David J. Barrett

David J. Barrett Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, Russell H. Ellison, Chief Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

/s/ Russell H. Ellison Russell H. Ellison Chief Executive Officer

November 17, 2014

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

In connection with the Quarterly Report on Form 10-Q of Assembly Biosciences, Inc. (the "Company") for the period ended September 30, 2014 as filed with the Securities and Exchange Commission on or about the date hereof (the "Report"), I, David J. Barrett, Chief Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

/s/ David J. Barrett David J. Barrett Chief Financial Officer

November 17, 2014