

# Virpax Pharmaceuticals Reports 2021 Third Quarter Results and Recent Developments

-- Company Strengthens Balance Sheet to Advance Product Pipeline--

BERWYN, PA --Virpax® Pharmaceuticals, Inc. ("Virpax" or the "Company") (NASDAQ:VRPX), today announced its financial results for the three and nine months ended September 30, 2021, and other recent developments.

"We continue to enhance our product pipeline, and because of our unique delivery technologies we have expanded our targeted indications beyond pain to include Central Nervous System (CNS) disorders and anti-viral indications. We recently raised \$40 million in an underwritten public offering of our common stock which greatly strengthened our balance sheet and has allowed us to accelerate our development timelines related to our non-clinical studies. Our goal is to successfully complete our Investigational New Drug (IND) filings and begin first-in-human trials as soon as possible," stated Anthony Mack, chairman and CEO of Virpax.

"With our cash on hand of \$41.7 million as of September 30, 2021, we believe we have sufficient funds to advance our 505(b)(2) product candidates, Epoladerm™ and Probudur™, through to a New Drug Application(NDA) filing. For Epoladerm, our spray film product candidate, based on our non-clinical studies and research we believe that osteoarthritis of the knee is a better global market opportunity for the Company and will focus our efforts for Epoladerm on this indication. With Probudur, our injectable bupivacaine liposomal hydrogel for postoperative pain management, we are working on improving the formulation to increase stability so that manufacturing would be less complex. We also anticipate being able to extend the patent protection for this product candidate.

"Our current remaining product pipeline leverages our licensed Molecular Envelope Technology (MET) which delivers medication through an intranasal delivery device that both permeates the blood-brain barrier and may bypass the liver. Our lead product candidate is Envelta™, which utilizes MET to deliver enkephalin nanoparticles for acute and chronic pain including pain associated with cancer. This product candidate is being funded through a Cooperative Research and Development Agreement (CRADA) with the National Center for Advancing Translational Sciences (NCATS). We recently announced that under this CRADA, the National Institutes of Health has awarded multiple contracts to support the development and manufacturing of Envelta. We are looking forward to the completion of the required IND enabling studies and submitting our IND package to the FDA in anticipation of first-in-human trials," continued Mr. Mack.

"Through ongoing work with our MET platform, we discovered that our product candidate, AnQlar<sup>TM</sup>, may provide a molecular barrier to respiratory infections such as SARS-CoV-2 and influenza by binding to the surface of viruses which in turn prevents the virus from binding to cell surface receptors that mediate viral infection. Following the receipt of a written pre-IND response from the FDA, our plan for AnQlar is to complete all studies required for an NDA submission as an over-the-counter (OTC) product. We believe there is a very large market for AnQlar and we are developing this product candidate to be used as a once daily intranasal administration to inhibit the ability of viruses to replicate and prevent viral spread.

"Finally, we recently acquired the worldwide rights to VRP324, which is an intranasal pharmaceutical-grade cannabidiol product candidate for the management of epilepsy in children (rare pediatric disease) and adults. VRP324 represents our first CNS disorder product indication. VRP324 utilizes our novel MET

intranasal delivery platform which, based on our early research, may bypass the liver and alleviate concerns related to drug-to-drug interaction compared to the currently available oral dosed cannabidiol product approved to manage seizure disorders.

"This is an exciting time at Virpax, and we believe that all of our product candidates have the potential to deliver significant improvements and benefits to currently existing treatment options," concluded Mr. Mack.

#### RECENT DEVELOPMENTS

- On July 30, 2021, Virpax announced the appointment of Gerald W. Bruce and Michael F. Dubin, CPA to its Board of Directors.
- On August 17, 2021, Virpax announced that it had received FDA response and guidance on AnQlar. The FDA has indicated that Virpax may pursue an NDA drug approval with the Office of Non-Prescription Drugs. The Company is developing this product candidate as a prophylactic treatment against SARS and influenza and has engaged Syneos Health to assist with the optimal clinical trial design.
- On September 9, 2021, Jeffrey A. Gudin, MD, Chief Medical Officer of Virpax, presented a poster on Leucine Enkephalin as a potential analgesic at PainWeek 2021 in Las Vegas, Nevada.
- On September 16, 2021, Virpax closed an underwritten public offering of 6,670,000 shares of its common stock for gross proceeds of \$40,020,000 before the deduction of underwriting discounts and offering expenses. The Company intends to use substantially all of the net proceeds from the underwritten offering to fund research and development of all of its product candidates and other development programs and for working capital and other general corporate purposes.
- On September 20, 2021, Virpax announced that it had acquired the exclusive worldwide rights from Nanomerics Ltd., for its MET for the nasal delivery of cannabidiol (CBD) for the management of epilepsy in children (rare pediatric disease) and adults. VRP324 is being developed to treat seizures associated with tuberous sclerosis complex (TSC), Lennox-Gastaut syndrome, and Dravet syndrome in patients one year of age and older.
- On October 6, 2021, Virpax announced an agreement with Sinclair Research to initiate IND enabling studies for AnQlar as a daily OTC prophylactic for treatment against SARS and influenza. Sinclair is expected to begin the preclinical animal studies at the beginning of 2022 as part of the enabling trials for an IND application with the FDA.

#### SCIENTIFIC ACHIEVEMENTS

• On June 21, 2021, Virpax announced that the IND enabling studies for Envelta being performed under a Cooperative Research and Development Agreement entered into by Virpax and NCATS for acute and chronic pain, will also be used as a source for INDs for two additional indications, for cancer pain and Post-Traumatic Stress Disorder. NCATS has commenced the IND enabling studies of Envelta to support Virpax's future application for clearance from the FDA to initiate Virpax's first-in-human clinical trials. The Company believes the same Phase I Single Ascending Dose /Multiple Ascending Dose study could be used to advance all three indications.

## FINANCIAL RESULTS FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

#### Three Months Ended September 30, 2021 and 2020

#### **Operating Expenses**

General and administrative expenses increased by \$0.7 million, or 91%, to \$1.6 million for the three months ended September 30, 2021, from \$0.8 million for the three months ended September 30, 2020. The primary reasons for the increase in general and administrative costs were (i) an increase in legal costs associated with litigation efforts and general corporate purposes of \$0.6 million, (ii) an increase in insurance costs related to directors' and officers' insurance of \$0.3 million, (iii) an increase in salaries and wages of \$0.1 million attributable to new hires, and (iv) an increase in grant consulting of \$47 thousand This was offset by a decrease in stock-based compensation of \$0.3 million.

Research and development expenses increased by \$0.8 million, or 99%, to \$1.7 million for the three months ended September 30, 2021, from \$0.9 million for the three months ended September 30, 2020. The increase was primarily attributable to an increase in pre-clinical activities related to Epoladerm of \$0.6 million, Probudur of \$12 thousand, VRP324 of \$0.2 million, and AnQlar of \$83 thousand. This was offset by a decrease in preclinical activity and milestone payments made for Envelta of \$0.7 million.

As a result of the foregoing, the Company's loss from operations for the three months ended September 30, 2021, was \$3.2 million, compared to a loss from operations of \$1.7 million for the three months ended September 30, 2020.

#### Nine Months Ended September 30, 2021 and 2020

#### **Operating Expenses**

General and administrative expenses increased by \$2.5 million, or 107%, to \$4.8 million for the nine months ended September 30, 2021, from \$2.3 million for the nine months ended September 30, 2020. The primary reasons for the increase in general and administrative costs were (i) an increase in legal costs associated mainly with litigation efforts and legal costs associated with general corporate purposes of \$1.9 million, (ii) an increase in insurance costs related to directors' and officers' insurance of \$0.7 million, (iii) an increase in exchange listing fees of \$0.1 million, and (iv) an increase in salaries and wages of \$0.1 million. This was offset by a decrease in stock-based compensation of \$0.3 million as compared to the prior period.

Research and development expenses increased by \$1.9 million, or 160%, to \$3.1 million for the nine months ended September 30, 2021, from \$1.2 million for the nine months ended September 30, 2020. The increase was primarily attributable to (i) a \$1.0 million milestone payment made to Nanomerics and preclinical activity of \$0.1 million associated with AnQlar, (ii) increases in pre-clinical activity related to Epoladerm of \$0.7 million, (iii) an increase in preclinical work in Probudur of \$0.7 million, and (iv) a milestone payment of \$0.2 million due to VRP324. This was slightly offset by a decrease of \$0.7 million in pre-clinical activities associated with Envelta.

As a result of the foregoing, the Company's loss from operations for the nine months ended September 30, 2021 was \$7.9 million, compared to a loss from operations of \$3.5 million for the nine months ended September 30, 2020.

#### Cash Flows

Cash used in operations was approximately \$9.6 million for the nine months ended September 30, 2021, compared to approximately \$1.2 million for the nine months ended September 30, 2020. The increase in cash used in operations was primarily the result of the increase in net loss, decrease in accounts payables balances, and an increase in prepaid insurance premiums and prepaid research and development.

#### Financing Activities

Cash provided by financing activities was \$51.3 million during the nine months ended September 30, 2021, attributable primarily to net proceeds received from the Company's initial public offering in February 2021 of \$15.8 million and the underwritten offering in September 2021 of \$37.0 million, after deducting underwriting discounts and offering expenses. These proceeds were offset by the repayment in full of the Company's promissory note in the principal amount of \$0.5 million in February 2021 and repayments of the Company's promissory notes and PPP loan of an aggregate of \$1.5 million. Cash provided by financing activities was \$1.4 million during the nine months ended September 30, 2020, attributable to \$1.4 million from the sale of 139,220 shares of the Company's common stock as well as proceeds received from the PPP loan of \$72,100.

At September 30, 2021, Virpax had cash of approximately \$41.7 million.

#### **About Virpax Pharmaceuticals**

Virpax a company specializing in developing product candidates for pain management, CNS disorders and anti-viral indications is using its proprietary technologies to optimize and target drug delivery. Virpax is initially seeking FDA approval of its three patented drug delivery platforms. Epoladerm<sup>TM</sup> is a topical diclofenac spray film formulation being developed to manage osteoarthritis pain. Probudur<sup>TM</sup> is a single injection long-acting liposomal bupivacaine formulation being developed to manage post-operative pain. Envelta<sup>TM</sup> is an intranasal Molecular-Envelope Technology (MET) enkephalin formulation being developed for the management of acute and chronic pain, including pain associated with cancer, as well as post-traumatic stress disorder (PTSD) under the name PES200. MET technology is also used in AnQlar<sup>TM</sup>, a product candidate to inhibit viral replication caused by influenza or SARS-CoV-2. Virpax recently acquired global rights to VRP324, a product candidate for the nasal delivery of a pharmaceutical-grade cannabidiol (CBD) for the management of epilepsy in children (rare pediatric disease) and adults. For more information, please visit www.virpaxpharma.com.

## **Forward-Looking Statement**

This press release contains certain 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 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's planned clinical trials, product development, clinical and regulatory timelines, market

opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors, including but are not limited to, statements related to: expectations with regard to the timing of data events; the success, cost, and timing of our product candidates development activities and ongoing and planned pre-clinical trials; our estimates regarding expenses; and the potential impact of the recent COVID-19 pandemic and the potential impact of sustained social distancing efforts, on the Company's operations, clinical development plans and timelines, which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

TABLES FOLLOW

## VIRPAX PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS

	_	ptember 30, 2021 Unaudited)	December 2020*	31,
ASSETS				
Current assets				
Cash	\$	41,713,435		796
Prepaid expenses and other current assets	_	1,559,598	18,	273
Total current assets		43,273,033	-	069
Deferred financing costs			392,	337
Total assets	\$	43,273,033	\$ 465,	406
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Accounts payable and accrued expenses	\$	1,811,809	\$ 3,115,	924
Notes payable		-	543,	990
Total current liabilities		1,811,809	3,659,	914
Notes payable, net of current portion		-	21,	590
Related party notes payable		-	1,000,	000
Total long-term liabilities		-	1,021,	590
Total liabilities		1,811,809	4,681,	504
Commitments and contingencies				
Stockholders' equity (deficit)				
Preferred stock, par value \$0.00001, 10,000,000 shares authorized, no shares				
issued and outstanding		_		_
Common stock, \$0.00001 par value; 100,000,000 shares authorized, 11,715,182				
shares issued and outstanding as of September 30, 2021; 3,145,153 shares				
issued and outstanding as of December 31, 2020		117		31
Additional paid-in capital		60,047,385	6,431,	
Accumulated deficit	_	(18,586,278)		
Total stockholders' equity (deficit)	_	41,461,224	(4,216,	
Total liabilities and stockholders' equity (deficit)	\$	43,273,033	\$ 465,	406

<sup>\*</sup> Derived from audited financial statements

### VIRPAX PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (UNAUDITED)

	M		M	or the Three onths Ended ptember 30, 2020	Mo		Mo	
OPERATING EXPENSES								
General and administrative	\$	1,551,570	Ş	810,674	Ş	4,814,114	\$	2,321,509
Research and development		1,698,204		851,780		3,089,769		1,187,333
Total operating expenses		3,249,774		1,662,454		7,903,883		3,508,842
Loss from operations		(3,249,774)		(1,662,454)	_	(7,903,883)		(3,508,842)
OTHER (EXPENSE) INCOME								
Interest expense		(28,892)	)	(45,709)		(93,640)		(129,600)
Other income (expense), net		62,922				59,089		4,000
Loss before tax provision		(3,215,744)	)	(1,708,163)		(7,938,434)		(125,600)
Benefit from income taxes				_		_		
Net loss	\$	(3,215,744)	\$	(1,708,163)	\$	(7,938,434)	\$	(3,634,442)
Basic and diluted net loss per share		(0.53)		(0.54)	\$	(1.59)	\$	(1.18)
Basic and diluted weighted average common		6 044 706		2 4 4 2 6 2 2		4.070.550		2 004 463
stock outstanding		6,011,796	_	3,142,090	_	4,979,553	_	3,091,108

### VIRPAX PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (UNAUDITED)

	M		For the Nine Months Ended September 30, 2020
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$	(7,938,434)	\$ (3,634,442)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense		-	129,600
Forgiveness of PPP loan		(61,816)	-
Stock-based compensation		833,084	1,138,096
Common stock issued in payment of consulting services and settlement of accounts payable		-	5,288
Change in operating assets and liabilities:			
Prepaid expenses and other current assets		(999,685)	(12,873)
Accounts payable and accrued expenses		(1,453,418)	1,140,300
Net cash used in operating activities	_	(9,620,269)	
	_		
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of notes payable		(503,764)	-
Proceeds from the issuance of debt		-	72,100
Proceeds from related party notes payable		100,000	-
Repayment of related party notes payable		(1,100,000)	
Proceeds from the issuance of stock		_	1,376,900
Offering costs related to secondary offering		(3,020,535)	-
Proceeds from secondary offering of common stock		40,020,000	-
Offering costs related to initial public offering		(2,216,793)	-
Proceeds from initial public offering of common stock		18,000,000	-
Net cash provided by financing activities		51,278,908	1,449,000
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Net change in cash		41,658,639	214,969
Cash, beginning of period		54,796	41,536
Cash, end of period	\$		\$ 256,505
cash, cha or period	=	11,713,133	230,303
Consider and all displacements and some scale financing activities			
Supplemental disclosure of cash and non-cash financing activities	<b>ب</b>	262.640	¢
Cash paid for interest	\$	363,640	\$ –
Cash paid for taxes	\$	_	<u>\$</u>
Common stock issued in payment of consulting services and settlements of accounts payable	\$	_	\$ 5,288
Deferred financing costs, included in accounts payable and accrued expense	s \$		\$ 176,391
Debt issued in payment of consulting services and settlement of accounts payable	\$		\$ 228,960

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## Or

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