UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT (DATE OF EARLIEST EVENT REPORTED): November 13, 2020

MOLECULIN BIOTECH, INC.
(Exact Name of Registrant as Specified in its Charter)

DELAWARE	**001-37758**	**47-4671997**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(I.R.S. Employer Identification No.)

5300 Memorial Drive, Suite 950, Houston, TX 77007
(Address of principal executive offices and zip code)

(713) 300-5160
(Registrant's telephone number, including area code)
(Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

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

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

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

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

Title of each class	Trading Symbol (s)	Name of each exchange on which registered
Common Stock, par value $.001 per share	MBRX	The NASDAQ Stock Market LLC

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2020, Moleculin Biotech, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020 and recent operational highlights. A copy of the press release is attached to this report as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated November 13, 2020
104	Cover page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURE

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

MOLECULIN BIOTECH, INC.

Date: November 13, 2020

By: /s/ Jonathan P. Foster
Jonathan P. Foster
Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated November 13, 2020
104	Cover page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Moleculin Biotech, Inc. Reports Financial Results for the Quarter Ended September 30, 2020

HOUSTON, November 13, 2020 /PRNewswire/ -- Moleculin Biotech, Inc., (Nasdaq: MBRX) (Moleculin or the Company), a clinical stage pharmaceutical company with a broad portfolio of drug candidates targeting highly resistant tumors and viruses, today announced its financial results for the quarter ended September 30, 2020 and provided a business update.

Management Discussion

"We are extremely encouraged by the progress we made in the third quarter. Despite the sustained headwinds from the COVID-19 pandemic, we were able to drive the development of Annamycin both in our AML and lung indications, further progress our clinical trials for WP1066, expand and accelerate our infectious disease platform, and bolster our experienced leadership team," commented Walter Klemp, Chairman and CEO of Moleculin.

"We were particularly encouraged by the progress we made advancing our lead candidate Annamycin, a 'next generation anthracycline' demonstrating little to no cardiotoxicity. In June, we conducted our End of Phase 1 meeting with the US Food and Drug Administration ("FDA"). As a result of this meeting, we will expand our protocol-mandated testing for cardiotoxicity throughout the remainder of the Phase 1 trial. This will provide additional safety data, including investigating the continued evidence of little to no cardiotoxicity, and efficacy data which both US and European regulators may consider as we prepare to transition to a Phase 2 clinical trial. We also received approval from Polish authorities to increase the dose-escalation from 30 mg/m2 per cohort to 60 mg/m2 per cohort which will accelerate finding the maximum tolerated dose."

"We were also excited by the promise Annamycin shows in targeting lung localized tumors. Currently there is an extreme unmet need for a more effective treatment of sarcomas that have metastasized to the lungs, and limited treatment options available for lung metastases resulting from a primary tumor, even though the primary tumor may have been treatable. In September, we were pleased to announce results from an independent laboratory demonstrating in animal studies the ability of Annamycin to generate a 30-fold greater concentration in lungs compared to the current standard of care drug, enabling the targeting of this cancer in its sanctuary site. These results further validate data we presented at the American Association of Cancer Research, which illustrated Annamycin's uniquely high uptake and retention in the lungs, resulting in consistently high in vivo activity against a wide range of lung-localized tumors in mice. Due to Annamycin's strong pre-clinical data in this indication, we successfully completed a pre-IND (Investigational New Drug) meeting with the FDA and discussed our development plan for Annamycin, including the clinical study design and dosing strategy for an initial Phase 1b/2 protocol for soft tissue sarcomas with lung metastases. Based on our conversations, and the compelling pre-clinical data, we are optimistic that we will be able to file an IND with the FDA for this indication before the end of the year."

“In addition to driving the development of Annamycin, we continued to advance WP1066, the lead molecule in Moleculin’s portfolio of immune stimulators and modulators of transcription. Importantly, we were able to report positive data from both our adult and pediatric Phase 1 clinical trials. In our adult Phase 1 clinical trial being conducted at a major cancer center in Houston, we reported positive preliminary data in adult patients with glioblastoma (“GBM”), which supports the progression of the trial to the fourth and final dose escalation cohort. In our Phase 1 clinical trial of WP1066 for the treatment of brain tumors in children being at conducted at the Aflac Cancer & Blood Disorders Center at Children’s Healthcare of Atlanta, the first three patients in the trial received treatment at a dose level of 4 mg/kg with no adverse events related to WP1066 and the study is now proceeding to the next higher dose of 6 mg/kg. Importantly, one patient with diffuse intrinsic pontine glioma (“DIPG”), showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size. We believe this to be particularly notable given the clinical trial history of DIPG, as approximately 200 clinical trials have been conducted with no drug showing significant activity in this disease.”

“Although we remain laser focused on advancing our clinical pipeline, we are very encouraged by the potential our infectious disease pipeline continues to offer. Our initial preclinical focus for the WP1122 program was to help provide a treatment for the growing COVID-19 pandemic. Following strong preclinical data and independent research demonstrating WP1122’s unique mechanism of action and in-vitro activity, we were pleased to further progress our studies as we prepare for submission of an IND to test WP1122 in COVID-19 patients. During the quarter, we also discovered that two other molecules within our portfolio of antimetabolites displayed significant in vitro antiviral activity against SARS-CoV-2 and other hard to treat viruses. Independent laboratory testing of our new drug candidates, called WP1096 and WP1097, not only showed significant antiviral activity against SARS-CoV-2, but also showed greater potential against HIV, Zika, and Dengue Fever. While we are encouraged by the strong preclinical data, we believe our best course of action for advancing this portfolio given its early stage will be through relying on collaborations and externally funded pathways. Subsequently, we entered into an agreement with the University of Campinas in São Paulo, Brazil to further enable collaboration into research on the anti-viral capabilities of WP1122, specifically for the coronavirus. We continue to be optimistic about the data demonstrated in the WP1122 portfolio and are planning to file an IND application or its equivalent for either cancer-related or virus-related clinical trials in the first half of 2021.”

Mr. Klemp concluded, “As we head into the final months of 2020, we believe we remain well-positioned to progress our three core technologies. To help drive this effort, we recently appointed Liz Cermak to our Board of Directors. Liz brings nearly four decades of healthcare experience, has helped oversee drugs through commercialization, and has licensed drugs to well respected big pharmaceutical companies. With our experienced leadership team, and the progress we made throughout the third quarter, we look forward to building on our momentum, and executing on our strategic plan as we head into 2021.”

Recent Milestones and Accomplishments:

Next Generation Anthracycline - Annamycin

- Announced results from an independent laboratory demonstrating the ability of Annamycin to target lung localized tumors, validating previous internal animal studies
- Successfully completed a pre-IND (Investigational New Drug) meeting with the FDA regarding the development plan for Annamycin, including the clinical study design and dosing strategy for the initial phase 1b/2 protocol for soft tissue sarcomas with lung metastases
- Announced positive preclinical data corroborating the efficacy of Annamycin in lung metastases at AACR
- Received approval to accelerate European clinical trial in AML, URPL doubled dose escalation. Currently in process with Polish regulatory authorities to open two additional clinical sites for the Phase 1/2 clinical study
- Announced positive independent report confirming absence of cardiotoxicity in Annamycin (unlike currently approved anthracyclines)
- Successfully completed Phase 1 portion of the AML Phase 1/2 trial in the US with positive results

Immune/Transcription Modulators - WP1066 Portfolio

- Announced preliminary data from the Phase 1 clinical trial of WP1066, in patients with glioblastoma (GBM). Data supports the progression of trial to the fourth and final dose escalation cohort
- Reported positive interim results in Emory University pediatric brain tumor Phase 1 clinical trial. One patient with diffuse intrinsic pontine glioma (DIPG) showed an apparent response to the treatment with both clinical improvement and radiologic reduction of tumor size
- Reported preclinical data demonstrating that WP1066 used in combination with traditional whole brain radiation therapy (WBRT) resulted in long-term survivors and enhanced median survival time relative to monotherapy in mice with implanted human brain tumors
- Patent protection filed by our licensor covering combination of immune stimulating/transcriptional modulator, including combination with radiation therapy
- Received Orphan Drug Designation from FDA

Infectious Disease and Metabolism/Glycosylation Inhibitors- WP1122, WP1096 and WP1097 Portfolio

- Entered into an agreement with the University of Campinas in São Paulo, Brazil to further research the anti-viral capabilities of WP1122, specifically for the coronavirus
- Announced in vitro results demonstrating the significant antiviral activity of WP1096 and WP1097, in a range of infectious diseases including against: SARS-CoV-2, HIV, Zika and Dengue Fever
- Independent research conducted at the University of Campinas in São Paulo, Brazil demonstrated that SARS-CoV-2 infection is supported by elevated glucose levels and that inhibition of glycolysis with 2-DG effectively eliminated viral load in vitro
- Corroborated antiviral activity of WP1122 against coronavirus in pre-clinical testing at IIT Research Institute in another virus host cell line
- Agreement with Sterling Pharma USA LLC for U.S. production of WP1122 to support expanded development efforts
- Two rounds of preclinical assessment of the potential for WP1122 to address COVID-19 at ImQuest BioSciences demonstrated that WP1122 has an antiviral effect on HCoV-229E. The virus yield reduction assay demonstrated a 5 to 10-fold inhibition of coronavirus production by WP1122 when compared to untreated virus control.
- University of Frankfurt found 2-DG to reduce replication of SARS-CoV-2, the virus that causes COVID-19, by 100% in in vitro testing
- Patent filed by our licensor covering WP1122 as anti-viral drug candidate

Corporate Strategy and Events

- Appointed Elizabeth (Liz) Cermak, an accomplished life sciences board director with deep pharmaceutical business development expertise, to Board of Directors
- Participated in a panel at ROTH Capital's, "COVID-19 Therapeutics in Development," healthcare event
- Presented virtually at the H.C. Wainwright & Co. 22nd Annual Global Investment Conference, the Oppenheimer Fall Healthcare Life Sciences & MedTech Summit and the LD Micro 500 Virtual Investor Conference in September
- Presented at the Life Sciences Investor Forum in June
- In November replaced our prior purchase agreement with Lincoln Park Capital with a new $22 million purchase agreement, including an initial investment of $2 million, with enhanced capabilities to draw upon

Anticipated 2020 Milestones

- IND submission for Annamycin for the treatment of tumor metastases to the lung
- Expanding infectious disease portfolio via preclinical testing of WP1122 in preparation for submitting an IND for a COVID-19 clinical trial in the first half of 2021
- Continued clinical testing in adult and pediatric brain tumors with WP1066 via physician sponsored trials

Financial Results for the Quarter Ended September 30, 2020

Research and development (R&D) expense was $4.4 million and $2.8 million for the three months ended September 30, 2020 and 2019, respectively. The increase of $1.6 million is mainly related to increased clinical trial activity, increased license fees and costs related to sponsored research agreements, costs related to manufacturing of additional drug product and two additional employees in R&D headcount.

General and administrative expense was $1.7 million for the three months ended September 30, 2020 and 2019, respectively.

Loss from operations for the third quarter was $6.2 million compared to a net loss of $4.5 million for the third quarter of 2019. This increase was largely due to the above-mentioned increase in R&D.

Net loss for the third quarter of 2020 was $3.4 million, compared to a net loss of $4.1 million in the third quarter of 2019, and was attributed to the above-mentioned increase in R&D and the change in fair value on revaluation of warrant liability associated with warrants issued in conjunction with stock offerings. Changes in our stock price can result in a material gain or loss during the quarter related to the revaluation of our warrant liability. The gain from the change in the fair value of the warrant liability for the third quarter of 2020 was $2.7 million compared to a gain of $0.1 million in the same quarter in 2019. This is a non-cash item.

Liquidity and Capital Resources

As of September 30, 2020, we had cash and cash equivalents of $12.8 million and prepaid expenses and other of $2.5 million. We also had $1.3 million of accounts payable and $2.1 million of accrued expenses. A significant portion of the accounts payable and accrued expenses are due to work performed in relation to our clinical trials. For the nine months ended September 30, 2020 and 2019, we used approximately $14.6 million and $12.5 million of cash in operating activities, respectively, which represents cash outlays for research and development and general and administrative expenses in such periods. For the nine months ended September 30, 2020 and 2019, net proceeds from financing activities were $17.1 million and $20.9 million, respectively, predominately from the sale of our common stock and the exercise of warrants. Cash used in investing activities for the nine months ended September 30, 2020 and 2019 was approximately $0.4 million and $0.04 million, respectively.

We believe that our existing cash and cash equivalents as of September 30, 2020 plus the $2.6 million cash raised and committed subsequent to the quarter will be sufficient to fund our planned operations into the third quarter of 2021, without the issuance of additional equity for cash. Any such issuances should extend the funding of our planned operations beyond the third quarter of 2021. Such plans are subject to our stock price, market conditions, changes in planned expenses depending on clinical enrollment progress, the use of drug product or a combination thereof.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a clinical stage pharmaceutical company focused on the development of a broad portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses. The Company's clinical stage drugs are: Annamycin, a Next Generation Anthracycline, designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic cancer and hematologic malignancies, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T-cell lymphoma. Moleculin is also engaged in preclinical development of additional drug candidates, including other Immune/Transcription Modulators, as well as WP1122 and related compounds capable of Metabolism/Glycosylation Inhibition.

For more information about the Company, please visit http://www.moleculin.com.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability to make an IND submission for WP1122 in the first half of 2021; establishing a recommended Phase 2 Dose for Annamycin in 2021; the ability to make an IND submission for Annamycin for the treatment of tumor metastases to the lung in 2020; and the ability to file for W1122 an IND application or its equivalent for either cancer-related or virus-related clinical trials in the first half of 2021. Although Moleculin believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. Moleculin Biotech has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission ("SEC") and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Contacts

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-- Financial Tables Follow--

Moleculin Biotech, Inc.

Unaudited Condensed Consolidated Balance Sheets

(in thousands)	September 30, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	$ 12,795	$ 10,735
Prepaid expenses and other current assets	2,455	2,749
Total current assets	15,250	13,484
Furniture and equipment, net	522	316
Intangible assets	11,148	11,148
Operating lease right-of-use asset	224	287
Total assets	$ 27,144	$ 25,235
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 3,438	$ 3,570
Total current liabilities	3,438	3,570
Operating lease liability - long-term, net of current portion	190	276
Warrant liability - long term	9,049	5,818
Total liabilities	12,677	9,664
Total stockholders' equity	14,467	15,571
Total liabilities and stockholders' equity	$ 27,144	$ 25,235

Unaudited Condensed Consolidated Statements of Operations

(in thousands, except share and per share amounts)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September, 30 2020	Nine Months Ended September, 30 2019
Revenues	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	4,435	2,785	10,971	7,816
General and administrative and depreciation	1,716	1,723	5,276	4,895
Total operating expenses	6,151	4,508	16,247	12,711
Loss from operations	(6,151)	(4,508)	(16,247)	(12,711)
Other income:				
Gain from change in fair value of warrant liability	2,743	124	1,489	3,059
Other income, net	10	5	32	5
Interest income, net	3	5	10	10
Net loss before taxes	$ (3,395)	$ (4,374)	$ (14,716)	$ (9,637)
Income tax benefit	—	229	—	229
Net loss	$ (3,395)	$ (4,145)	$ (14,716)	$ (9,408)
Net loss per common share - basic and diluted	$ (0.06)	$ (0.09)	$ (0.26)	$ (0.24)
Weighted average common shares outstanding - basic and diluted	61,474,857	45,464,746	56,979,507	39,034,303