

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): September 1, 2020

MOLECULIN BIOTECH, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

(State or Other Jurisdiction of Incorporation or Organization)

001-37758

(Commission File No.)

47-4671997

(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-4(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 7.01 Regulation FD Disclosure.

On September 1, 2020, Moleculin Biotech, Inc. (the "Company") conducted an investor webinar using the presentation set forth as Exhibit 99.1 herein. The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be "filed" for the purpose of the Securities Exchange Act of 1934, as amended ("Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended ("Securities Act"), unless specifically identified therein as being incorporated by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Investor Presentation dated September 2020

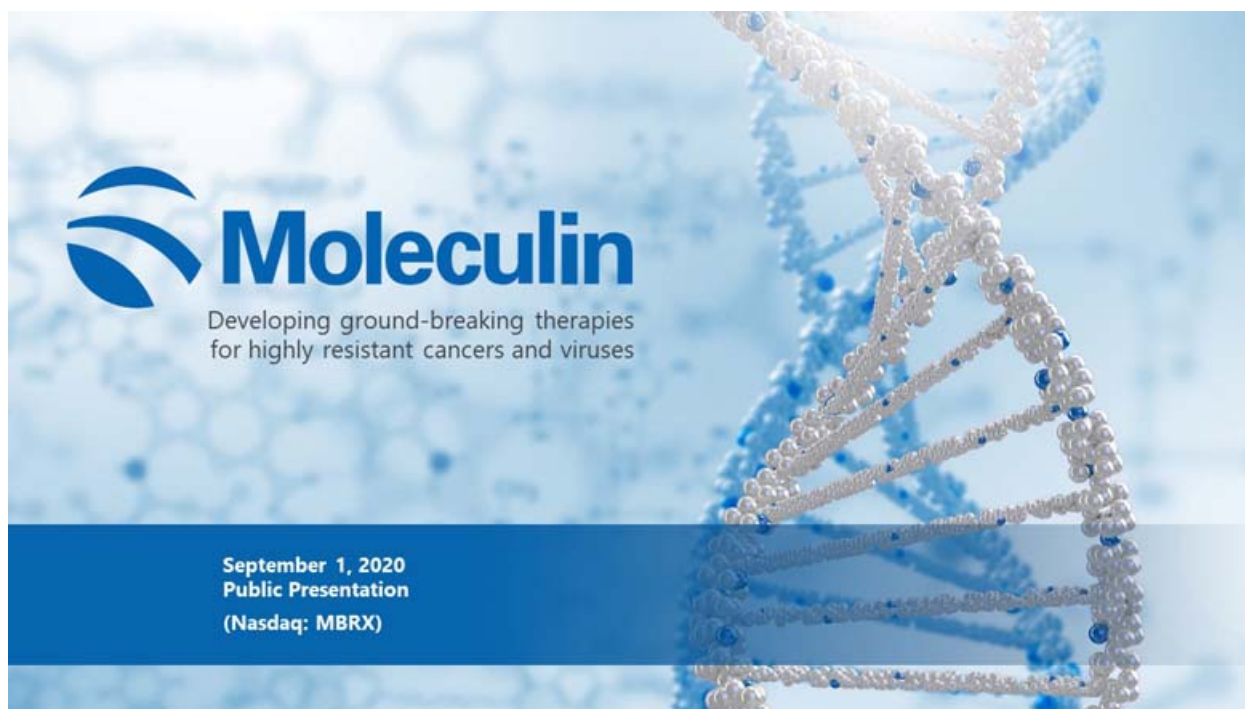
SIGNATURE

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: September 1, 2020

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

The image features a blue and white DNA double helix structure on the right side, set against a background of a light blue molecular lattice. On the left, the Moleculin logo is displayed, consisting of a stylized blue 'M' shape. Below the logo, the company name 'Moleculin' is written in a bold, blue, sans-serif font. Underneath the name, the tagline 'Developing ground-breaking therapies for highly resistant cancers and viruses' is written in a smaller, blue, sans-serif font. A solid blue horizontal bar spans the width of the image, containing white text that reads 'September 1, 2020', 'Public Presentation', and '(Nasdaq: MBRX)'.

Moleculin
Developing ground-breaking therapies
for highly resistant cancers and viruses

September 1, 2020
Public Presentation
(Nasdaq: MBRX)



Disclaimer

All statements contained herein other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. 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. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward looking statements. More detailed information about Moleculin is set forth in our filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's web site at <http://www.sec.gov>.

A close-up photograph of a microscope, showing the objective lens, eyepiece, and stage. The image is overlaid with a blue horizontal bar containing the text "Highly Experienced Leadership".

Highly Experienced Leadership

Executive Management Team



Walter Klemp,
Chairman, President & CEO



Don Picker, PhD
Chief Science Officer



Jonathan P. Foster,
CPA, CGMA
EVP & CFO



Robert Shepard,
MD, FACP
Chief Medical Officer



Sandra Silberman,
MD & PhD
Chief Medical Officer – New
Products



Selected Prior Experience



Science Advisory Board



Waldemar Priebe,
PhD
THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center



Paul Waymack,
MD, SC
FDA



James Abbruzzese,
MD
DANA-FARBER
CANCER INSTITUTE
Duke University
School of Medicine

Pancreatic



Elihu Estey,
MD
FRED HUTCH
CURES START HERE
JOHNS HOPKINS
MEDICAL UNIVERSITY



Marty Tallman,
MD
Memorial Sloan Kettering
Cancer Center



Jorge Cortes,
MD
THE NEW ENGLAND
JOURNAL OF MEDICINE
GEORGIA
CANCER CENTER
AUGUSTA UNIVERSITY

Hematology



Richard Whitley,
MD
NIH National Institute of
Allergy and
Infectious Diseases



Dominique Schols,
PhD
LEUVEN
Rega Instituut



Hongbo Zhai,
MD
UCSF

Virology

Investment Highlights

Potential Blockbuster Technologies **3**

2020 Phase 1 clinical trials **5**

Drugs showing early human activity **2**

2020-2021 Phase 2 trials expected **2**

Non-cardiotoxic anthracycline

STAT3 Inhibitor

Antimetabolites –
cancers and viruses

World class collaboration
Highly experienced team
Exclusive IP/Fast Track

Three Core Technologies

1

Next Generation Anthracycline

- Non-cardiotoxic
- Avoids multidrug resistance
- Enables "organ-targeted" therapy

Annamycin

2

Immune / Transcription Modulators

- p-STAT3 inhibitor
- Key cancer and viral signaling pathway
- ↑ immune response/memory

WP1066

3

Antimetabolites / Glycosylation Inhibitor

- Prodrug of glucose decoy enables drug-like properties
- Disruption of metabolisms - relevant to certain cancers and viruses

WP1122

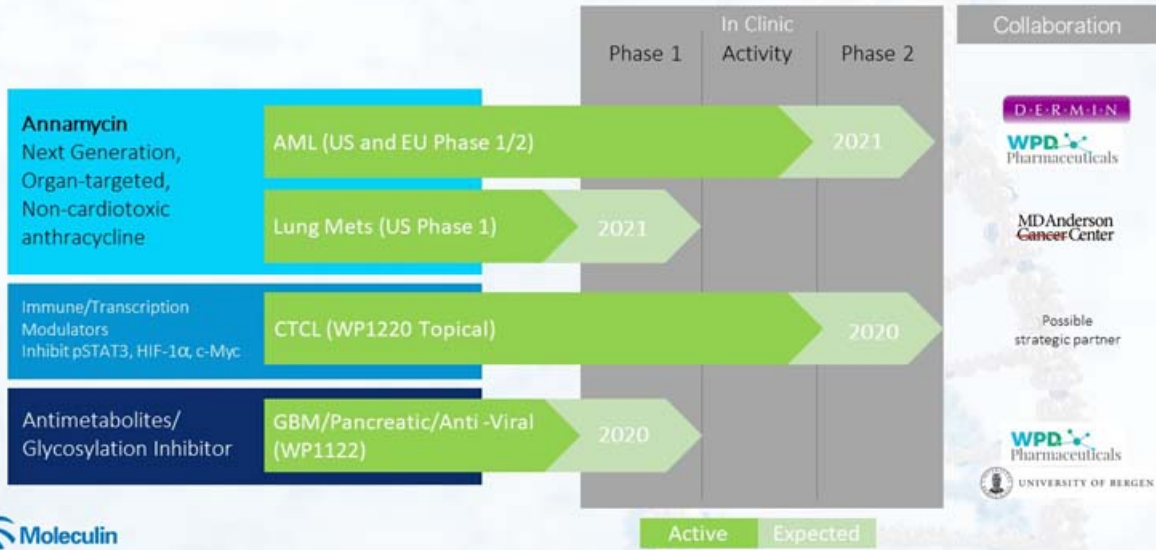
Potential for Drug Combination Therapies

Leading Partnerships, Collaborations

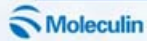
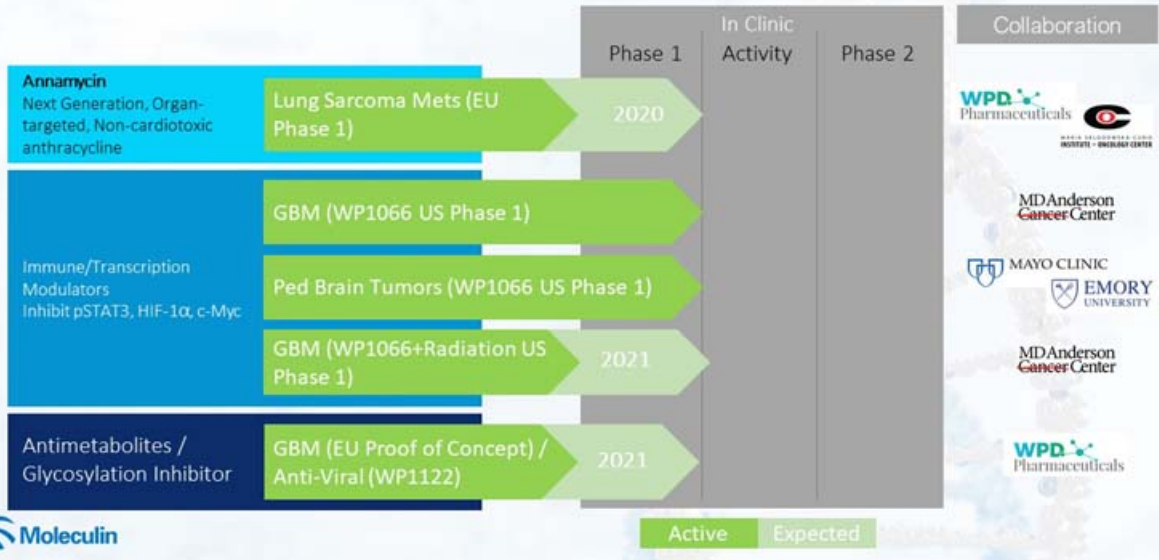
Our world-leading partnerships & collaborations significantly expand our research capabilities and increase our knowledgebase



Development Pipeline – Internally Funded



Development Pipeline – Externally Funded



Active Expected

Key Developments

3 drug candidates in 5 clinical trials

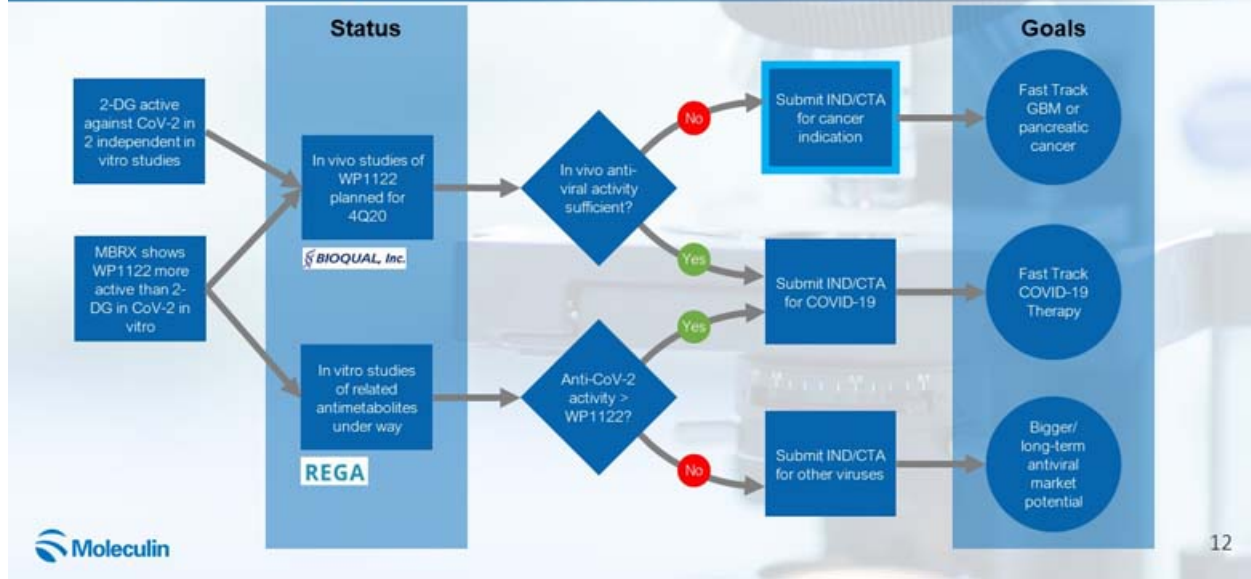
Next Generation Anthracycline – Annamycin (2 Clinical Trials)

- **Positive interim safety and efficacy data in US and Europe AML Trials**
 - 45% efficacy in 11 relapsed AML patients treated at/or above 120 mg/m² (1 CRi, 3 PRs, 1 BTB); clearing circulating blasts
 - No evidence of cardiotoxicity
- **U.S. concluded successfully Phase 1 portion; Europe in fifth cohort level of 240 mg/m² ; Approval to accelerate dosage intervals**
- **ODD and Fast Track Designation from FDA for the treatment of relapsed or refractory acute myeloid (AML)**
- **Active against metastases to the lungs in pre-clinical testing**
 - Significantly improved survival in an aggressive form for triple negative breast cancer metastasized to the lungs in animal models; Moving to IND in 2020

Immune/Transcription Modulators - (3 Clinical Trials)

- **Emory University began Phase 1 pediatric brain tumor trial**
- **Continue MD Anderson Phase 1 in adult brain tumors**
- **Efficacy and safety demonstrated in European Phase 1 clinical trial of WP1220 for the topical treatment of cutaneous T-Cell Lymphoma (CTCL) – moving to Phase 2**
- **FDA granted Orphan Drug Designation for WP1066 for the treatment of glioblastoma, the most aggressive form of brain tumor**
- **WP1066 appears to:**
 - (a) Counteract resistance to checkpoint blockade therapy (specifically, immune checkpoint target PD-L1) and
 - (b) Be capable of immune reprogramming

Key Developments – Antimetabolites



Additional Potential 2020 Value Inflection Points



Financial Review



Financial Statement Summary

In thousands, except for share and per share data and shares outstanding	For the Year Ended 12/31/19	For the 6 mos 6/30/2020
	(Unaudited)	(Unaudited)
Statement of Operations Data		
Revenue	-	-
Research and development	\$11,013	\$6,535
General and administrative and depreciation	6,511	3,561
Loss from operations	(17,524)	(10,096)
Net loss	(13,205)	(11,321)
Net loss per common share – basic and diluted	\$ (0.32)	\$ (0.21)
Basic and diluted weighted average shares outstanding	40,721,406	54,707,132
Balance Sheet Data		
Cash and cash equivalents	\$ 10,735	\$ 16,734
Prepaid expenses and other	2,749	3,015
Total current assets	13,484	19,749
Total assets	\$25,235	\$31,380
Total current liabilities	3,570	3,739
Total liabilities	9,664	15,751
Total stockholders' equity	15,571	15,629
Total liabilities and stockholders' equity	\$25,235	\$31,380

- "Capital efficient" approach
- Leverage R&D with contractors, sponsored research, and investigator led trials
- Five clinical trials on a \$12M run-rate R&D spend
- **\$17 million raise in Jan-Aug**
- 61.7 million shares outstanding August 7, 2020

The above financial information is summarized from the Company's most recent forms filed with the SEC (www.sec.gov)

Various Sources of Financing

Opportunistic Approach

- Approx. \$20 million raised 2019; \$17 million YTD 2020
- Three analysts have reported on MBRX – Roth, Maxim, & Opco
- Overnight and intraday deals
- \$15 million ATM – Opco
- Equity Line - Lincoln Park Capital
- Successful out-licensing of technology in low priority areas
- Partnerships on drugs showing activity



The above financial information is summarized from the Company's most recent 10-K AND 10-Q filed with the SEC (www.sec.gov)

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