
**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 7 , 2022

SESEN BIO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36296
(Commission
File Number)

26-2025616
(I.R.S. Employer
Identification No.)

245 First Street, Suite 1800
Cambridge, MA
(Address of principal executive offices)

02142
(Zip Code)

Registrant's telephone number, including area code: (617) 444-8550

Not Applicable
(Former name or former address, if changed since last report.)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	SESN	The Nasdaq Stock Market LLC

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

Emerging growth company

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

Item 2.02 – Results of Operations and Financial Condition.

On November 7, 2022, Sesen Bio, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2022. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 – Financial Statements and Exhibits.

99.1	Press Release dated November 7, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Date: November 7, 2022

Sesen Bio, Inc.

By: /s/ Thomas R. Cannell, D.V.M.
Thomas R. Cannell, D.V.M.
President and Chief Executive Officer

Sesen Bio Reports Third Quarter 2022 Financial Results and Business Update

Sesen Bio announced proposed merger with Carisma Therapeutics

Combined company will focus on the advancement of Carisma's development of engineered macrophages for the treatment of cancer and other serious disorders

Transaction is expected to close in the next two to three months, subject to Sesen Bio stockholder approval and other customary closing conditions

CAMBRIDGE, Mass., Nov. 7, 2022 – Sesen Bio (Nasdaq: [SESN](#)) today reported operating results for the third quarter ended September 30, 2022, and provided a business update.

Business Updates

- On September 21, 2022, Sesen Bio announced that it had entered into a definitive merger agreement with Carisma Therapeutics (Carisma). The combined company will focus on the development of Carisma's chimeric antigen receptor macrophage (CAR-M) therapies, which are believed to be the only therapies of their kind with demonstrated proof of mechanism and safety data in clinical trials.

Immediately following the merger, pre-merger Sesen Bio stockholders are expected to own approximately 41.7% of the combined company and pre-merger Carisma stockholders are expected to own approximately 58.3% of the combined company, in each case before giving effect to a \$30.6 million concurrent financing by Carisma and the conversion into shares of common stock of the combined company of a \$35.0 million outstanding convertible note from one of Carisma's key strategic partners, Moderna.

Immediately prior to the closing of the merger, Sesen Bio stockholders of record as of a date agreed to by Sesen Bio and Carisma will be issued a Contingent Value Right (CVR) for each outstanding share of Sesen Bio common stock held as of such date, representing the right to receive contingent cash payments upon the receipt by Sesen Bio of certain proceeds payable by Roche, if any, related to the asset purchase agreement with Roche for EBI-031 and all other IL-6 antagonist monoclonal antibody technology (Roche Asset Purchase Agreement) subject to customary deductions, including for expenses and taxes.

The combined company is expected to have approximately \$180.0 million in cash, cash equivalents and marketable securities at the closing of the merger, which is expected to advance Carisma's pipeline through upcoming catalysts and development milestones across its clinical programs.

The combined company will be led entirely by Carisma's current management team, which has extensive cell therapy experience and a strong track record in oncology and drug development. This includes Carisma CEO Steven Kelly, who was named Ernst & Young Entrepreneur of the

Year 2022 Greater Philadelphia¹, and Carisma Chief Scientific Officer and co-founder Michael Klichinsky, Pharm.D., Ph.D.

- On July 18, 2022, Sesen Bio announced it was voluntarily pausing further clinical development of Vicineum in the US and that it intends to seek a partner to continue **Vicineum's development**. Sesen Bio remains focused on closing the proposed transaction with Carisma while it continues to evaluate potential opportunities for Vicineum.
- On November 1, 2022, Carisma announced the acceptance of multiple abstracts to be presented at the upcoming Society for Immunotherapy of Cancer (SITC) 37th Anniversary Annual Meeting in Boston, Massachusetts, which is being held November 8 to November 12, 2022. Accepted abstracts include two abstracts of its clinical trial data, including one for oral presentation, four abstracts of pre-clinical study data, and one abstract overviewing the design of a Phase 1 clinical trial for CT-0508.

Third Quarter 2022 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$184.9 million as of September 30, 2022, compared to cash and cash equivalents of \$162.6 million as of December 31, 2021.
 - **Total Revenue:** Total revenue for the three months ended September 30, 2022 was \$40.0 million, which was due to the execution of the Roche Asset Purchase Agreement.
 - **R&D Expenses:** Research and development expenses were \$2.9 million for the three months ended September 30, 2022, compared to \$5.0 million for the three months ended September 30, 2021. The decrease of \$2.0 million was primarily due to a decrease in costs associated with manufacturing (\$1.9 million) and a decrease in other R&D related costs (\$0.1 million), driven by the strategic decision to voluntarily pause further development of Vicineum in the US in the third quarter of 2022.
 - **G&A Expenses:** General and administrative expenses were \$8.1 million for the three months ended September 30, 2022, compared to \$8.7 million for the three months ended September 30, 2021. The decrease of \$0.6 million was primarily due to a decrease in marketing and commercialization expenses, which were incurred in preparation for potential commercial launch of Vicineum but were discontinued as a result of the Complete Response Letter (CRL) from the US Food and Drug Administration (FDA) received in August 2021 (\$2.3 million) and a decrease in professional fees for accounting services (\$0.4 million). This was partially offset by an increase in legal expense (\$1.3 million), driven by legal fees associated with our assessment of strategic alternatives incurred in the third quarter of 2022 (\$2.2 million), partially offset by a decrease in legal fees associated with the internal review (\$0.4 million) and other legal expenses (\$0.5 million). Additionally, financial advisor fees increased due to the Company's assessment of strategic alternatives in the third quarter of 2022 (\$0.8 million).
 - **Restructuring Charges:** Restructuring charges were \$10.9 million for the three months ended September 30, 2022, compared to \$5.5 million for the three months ended September 30, 2021. Restructuring charges for the third quarter of 2022 consisted of severance and other employee-related costs (\$6.9 million) and termination of certain contracts and other associated costs (\$4.0 million) associated with the restructuring plan approved on July 15, 2022 following the decision to voluntarily pause further development of Vicineum in the US. Restructuring charges for the third
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quarter of 2021 consisted of severance and other employee-related costs (\$2.8 million) and termination of certain contracts (\$2.7 million) associated with the restructuring plan approved on August 30, 2021 following the receipt of the CRL.

- Non-Cash Related Expenses:
 - The Company did not record any intangibles impairment charge for the three months ended September 30, 2022, and the Company recorded an intangibles impairment charge of \$31.7 million in the three months ended September 30, 2021. In light of the CRL, the Company performed an interim impairment test for In-Process Research and Development (IPR&D) assets, which resulted in the decrease in fair value of Vicineum's US rights.
 - The non-cash change in fair value of contingent consideration was a gain of \$1.8 million for the three months ended September 30, 2022, compared to a gain of \$114.0 million for the three months ended September 30, 2021. The gain from the fair value of contingent consideration of \$1.8 million for the three months ended September 30, 2022, was due to the Company's conclusion that it no longer expects to make earnout payments to Qilu Pharmaceutical Co., Ltd. for commercialization of Vicineum in the Greater China region. Accordingly, the Company reduced the remaining \$1.8 million of contingent consideration liabilities to zero as of September 30, 2022. The gain from the fair value of contingent consideration of \$114.0 million for the three months ended September 30, 2021, was primarily due to management's assessment of a lower probability of regulatory success of Vicineum, and a refinement of associated timelines, following the CRL.
- Income Tax Benefit: The Company did not record a benefit or loss for the three months ended September 30, 2022. In the third quarter of 2021, the Company determined that the fair value of the Company's intangible asset of Vicineum US rights was zero, which resulted in an impairment charge of \$31.7 million. In connection with this impairment charge, in the third quarter of 2021, the Company reduced the associated deferred tax liability, which resulted in an income tax benefit of \$8.6 million.
- Net Income: Net income was \$20.5 million, or \$0.10 per basic and \$0.10 per diluted share, for the third quarter of 2022, compared to \$71.7 million, or \$0.36 per basic and \$0.36 per diluted share, for the third quarter of 2021. The decrease was primarily attributable to unfavorable changes in non-cash related expenses of \$89.1 million (including tax benefit) and increased restructuring charges of \$5.4 million. This was partially offset by revenue of \$40.0 million related to the execution of the Roche Asset Purchase Agreement.

1: Award presented by Ernst & Young; winners are selected by a panel of independent judges based on their demonstration of long-term value through entrepreneurial spirit, purpose, growth and impact, among other core contributions and attributes.

About Sesen Bio

Sesen Bio, Inc. is a late-stage clinical company focused on targeted fusion protein therapeutics for the treatment of patients with cancer. Sesen Bio's most advanced product candidate, Vicineum™, also known as VB4-845, is a locally-administered targeted fusion protein composed of an anti-epithelial cell adhesion molecule antibody fragment tethered to a truncated form of Pseudomonas exotoxin A for the treatment of non-muscle invasive bladder cancer. On July 15, 2022, Sesen Bio made the strategic decision to voluntarily pause further development of Vicineum in the US. The decision was based on a thorough reassessment of Vicineum following recent discussions with the FDA, which had implications on the size, timeline and costs of an additional Phase 3 clinical trial, which the FDA previously confirmed would be required for a potential resubmission of a BLA for Vicineum for the treatment of

NMIBC. Sesen Bio continues to believe that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure, and as such, intends to seek a partner that can execute further development to realize the full potential of Vicineum. As a result of this decision, Sesen Bio has turned its primary focus to the careful assessment of potential strategic alternatives with the goal of maximizing shareholder value. For more information, please visit the Company's website at www.sesenbio.com.

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for Sesen Bio, Carisma or the combined company, Sesen Bio's, Carisma's or the combined company's strategy or future operations, and other statements containing the words "anticipate," "believe," "contemplate," "expect," "intend," "may," "plan," "predict," "target," "potential," "possible," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. For example, statements concerning the proposed merger with Carisma, the concurrent financing by Carisma, the CVRs and other matters, including without limitation: statements relating to the satisfaction of the conditions to and consummation of the proposed transaction, the expected timing of the consummation of the proposed transaction, the expected cash balance of the combined company at the closing of the merger, the expected uses of the cash balance of the combined company, the expected management team of the combined company, the expected ownership percentages of the combined company, Sesen Bio's and Carisma's respective businesses, the strategy of the combined company, future operations, advancement of the combined company's product candidates and product pipeline, clinical development of the combined company's product candidates, including expectations regarding timing of initiation and results of clinical trials of the combined company, the completion of the concurrent financing by Carisma, the receipt of any payments under the CVRs, Sesen Bio's intentions to seek a partner for the further development of Vicineum and Sesen Bio's belief that Vicineum has benefits for patients and healthcare providers that can be maximized through a company with a larger infrastructure are forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including without limitation: (i) the risk that the conditions to the closing of the proposed transaction are not satisfied, including the failure to obtain stockholder approval of matters related to the proposed transaction in a timely manner or at all; (ii) uncertainties as to the timing of the consummation of the proposed transaction and the ability of each of Sesen Bio and Carisma to consummate the proposed transaction, including completing the concurrent financing; (iii) risks related to Sesen Bio's ability to correctly estimate its expected net cash at closing and Sesen Bio's and Carisma's ability to correctly estimate and manage their respective operating expenses and expenses associated with the proposed transaction; (iv) risks related to Sesen Bio's continued listing on the Nasdaq Stock Market until closing of the proposed transaction; (v) the risk that as a result of adjustments to the exchange ratio, Sesen Bio stockholders or Carisma stockholders could own less of the combined company than is currently anticipated; (vi) the risk that the conditions to payment under the CVRs will not be met and that the CVR may otherwise never deliver any value to Sesen Bio stockholders; (vii) risks associated with the possible failure to realize certain anticipated benefits of the proposed transaction, including with respect to future financial and operating results; (viii) uncertainties regarding the impact any delay in the closing would have on the anticipated cash

resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company's cash resources; (ix) the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement; (x) the effect of the announcement, pendency or completion of the merger on Sesen Bio's or Carisma's business relationships, operating results and business generally; (xi) costs related to the merger; (xii) the outcome of any legal proceedings that may be instituted against Sesen Bio, Carisma or any of their respective directors or officers related to the merger agreement or the transactions contemplated thereby; (xiii) the ability of Sesen Bio or Carisma to protect their respective intellectual property rights; (xiv) competitive responses to the proposed transaction and changes in expected or existing competition; (xv) the success and timing of regulatory submissions and pre-clinical and clinical trials; (xvi) regulatory requirements or developments; (xvii) changes to clinical trial designs and regulatory pathways; (xviii) changes in capital resource requirements; (xix) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance its product candidates and its preclinical programs; (xx) legislative, regulatory, political and economic developments; (xxi) the risk that Sesen Bio may not ultimately be successful in seeking a partner to continue development of Vicineum; (xxii) Sesen Bio may become involved in disagreements or disputes with its licensees, licensors and other counterparties relating to the development and/or commercialization of Vicineum, which may be time consuming, costly and could divert Sesen Bio's efforts and attention from consummating the proposed merger with Carisma and harm its efforts to seek a partner to continue development of Vicineum; and (xxiii) other factors discussed in the "Risk Factors" section of Sesen Bio's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the SEC. In addition, the forward-looking statements included in this communication represent Sesen Bio's and Carisma's views as of the date hereof. Sesen Bio and Carisma anticipate that subsequent events and developments will cause the respective company's views to change. However, while Sesen Bio may elect to update these forward-looking statements at some point in the future, Sesen Bio specifically disclaims any obligation to do so, except as required under applicable law. These forward-looking statements should not be relied upon as representing Sesen Bio's views as of any date subsequent to the date hereof.

Important Additional Information

In connection with the proposed transaction, on October 14, 2022, Sesen Bio filed with the SEC a registration statement on Form S-4, which includes a preliminary proxy statement of Sesen Bio and which also constitutes a prospectus of Sesen Bio with respect to shares of Sesen Bio's common stock to be issued in the proposed transaction (Preliminary Proxy Statement/Prospectus). The Preliminary Proxy Statement/Prospectus is not final and may be amended. The definitive proxy statement/prospectus (if and when available) will be delivered to Sesen Bio's stockholders. Sesen Bio may also file other relevant documents regarding the proposed transaction with the SEC. **INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THESE MATERIALS, INCLUDING THE REGISTRATION STATEMENT, THE DEFINITIVE PROXY STATEMENT/PROSPECTUS, AND ALL OTHER RELEVANT DOCUMENTS THAT ARE OR WILL BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION, INCLUDING ANY AMENDMENTS OR SUPPLEMENTS TO THESE MATERIALS, BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION.** Investors and security holders are able to obtain the

Preliminary Proxy Statement/Prospectus, the definitive proxy statement/prospectus (when it becomes available) and other documents that are filed or will be filed by Sesen Bio with the SEC free of charge from the SEC's website at www.sec.gov or from Sesen Bio at the SEC Filings section of www.sesenbio.com.

No Offer or Solicitation

This press release shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, a public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, facsimile transmission, telephone or internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

Participants in the Solicitation

Sesen Bio and Carisma and their respective directors, executive officers and other members of management may be deemed to be participants in the solicitation of proxies in respect of the proposed transaction. Information about Sesen Bio's directors and executive officers is available in Sesen Bio's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, its definitive proxy statement dated April 28, 2022 for its 2022 Annual Meeting of Stockholders and its Current Report on Form 8-K filed with the SEC on August 31, 2022. Other information regarding the participants in the proxy solicitation and a description of their interests in the transaction, by security holdings or otherwise, is included in the Preliminary Proxy Statement/Prospectus and other relevant materials that are or will be filed with the SEC regarding the proposed transaction. Investors should read the definitive proxy statement/prospectus carefully (when it becomes available) before making any voting or investment decisions. You may obtain free copies of these documents from Sesen Bio or the SEC's website as indicated above.

Investors:

Erin Clark, Vice President, Corporate Strategy & Investor Relations
ir@sesenbio.com

SESEN BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited; In thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 71,107	\$ 162,636
Short term marketable securities	106,427	-
Accounts receivable	-	21,011
Other receivables	14,297	3,482
Prepaid expenses and other current assets	527	18,476
Total current assets	192,358	205,605
Non-current assets:		
Restricted cash	30	20
Marketable securities	7,336	-
Property and equipment, net	-	43
Intangible assets	-	14,700
Goodwill	-	13,064
Long term prepaid expenses	-	7,192
Other assets	-	123
Total non-current assets	7,366	35,142
Total Assets	\$ 199,724	\$ 240,747
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 514	\$ 2,853
Accrued expenses	33,800	8,255
Other current liabilities	381	460
Total current liabilities	34,695	11,568
Non-current liabilities:		
Contingent consideration	-	52,000
Deferred tax liability	-	3,969
Deferred revenue	-	1,500
Total non-current liabilities	-	57,469
Total Liabilities	34,695	69,037
Stockholders' Equity:		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	-	-
Common stock, \$0.001 par value per share; 400,000,000 shares authorized at September 30, 2022 and December 31, 2021; 202,757,012 and 199,463,645 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	202	199
Additional paid-in capital	493,629	487,768
Other comprehensive loss	(235)	-
Accumulated deficit	(328,567)	(316,257)
Total Stockholders' Equity	165,029	171,710
Total Liabilities and Stockholders' Equity	\$ 199,724	\$ 240,747

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF INCOME (OPERATIONS)
(Unaudited; In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
License and related revenue	\$ 40,000	\$ -	\$ 40,000	\$ 6,544
Total revenue	<u>\$ 40,000</u>	<u>\$ -</u>	<u>\$ 40,000</u>	<u>\$ 6,544</u>
Operating expenses:				
Research and development	\$ 2,931	\$ 4,967	\$ 37,636	\$ 18,273
General and administrative	8,141	8,699	32,705	20,797
Restructuring charge	10,947	5,522	10,947	5,522
Intangibles impairment charge	-	31,700	27,764	31,700
Change in fair value of contingent consideration	(1,800)	(114,000)	(52,000)	(52,240)
Total operating expenses	<u>\$ 20,219</u>	<u>\$ (63,112)</u>	<u>\$ 57,052</u>	<u>\$ 24,052</u>
Income (Loss) from Operations	\$ 19,781	\$ 63,112	\$ (17,052)	\$ (17,508)
Other income (expense), net	676	1	867	(45)
Income (Loss) Before Taxes	\$ 20,457	\$ 63,113	\$ (16,185)	\$ (17,553)
Benefit from income taxes	-	8,561	3,875	8,273
Net Income (Loss) After Taxes	<u>\$ 20,457</u>	<u>\$ 71,674</u>	<u>\$ (12,310)</u>	<u>\$ (9,280)</u>
Net income (loss) attributable to common stockholders - basic	\$ 20,442	\$ 71,622	\$ (12,310)	\$ (9,280)
Net income (loss) attributable to common stockholders - diluted	\$ 20,442	\$ 71,623	\$ (12,310)	\$ (9,280)
Net income (loss) per common share - basic	\$ 0.10	\$ 0.36	\$ (0.06)	\$ (0.05)
Weighted-average common shares outstanding - basic	200,464	196,778	199,801	176,547
Net income (loss) per common share - diluted	\$ 0.10	\$ 0.36	\$ (0.06)	\$ (0.05)
Weighted-average common shares outstanding - diluted	200,947	201,017	199,801	176,547

SESEN BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Unaudited; In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net income (loss)	\$ 20,457	\$ 71,674	\$ (12,310)	\$ (9,280)
Unrealized (gain) loss on marketable securities	(46)	-	235	-
Total comprehensive income (loss)	<u>\$ 20,503</u>	<u>\$ 71,674</u>	<u>\$ (12,545)</u>	<u>\$ (9,280)</u>

