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March 21, 2022
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SQZ Biotechnologies Co. (SQZ - NYSE)

2021 Results

Based on our DCF model and a 15% discount rate, SQZ is valued at approximately $30.00 per share. Our model applies an 11% probability of ultimate approval and commercialization for products manufactured with the Cell Squeeze® process. The model includes contributions from the United States and around the globe.

Current Price (3/18/2022)	$4.97
Valuation	**$30.00**

OUTLOOK

SQZ Biotechnologies is a clinical-stage cell therapy company with two Ph1 assets in HPV+ tumors that are based on the Cell Squeeze platform. The platform is divided into APCs, AACs & TACs, which stimulate immune activation, antigen delivery & tolerization using natural mechanisms. The APC process is capable of directly engineering MHC Class I presentation & co-stimulation in a physiologically relevant manner to generate CD8+ T cell responses.

The process forces cells through a narrow microfluidic channel which temporarily opens pores in the cells, thereby allowing cargo to be delivered. Cargo can include nucleic acids, peptides, proteins, gene editing complexes and small molecules among others and can be delivered to over 25 mammalian cell types.

SQZ' lead programs are targeting HPV+ solid tumors in two trials using the APC & AAC platforms. Each trial is in Ph1. SQZ is partnering with Roche and has an agreement to receive future milestones and royalties. Other potential indications which may advance to the clinic include HBV, KRAS mutant solid tumors, celiac disease, T1D and rapid response vaccines.

SUMMARY DATA

52-Week High	**16.17**
52-Week Low	**3.86**
One-Year Return (%)	**-66.7**
Beta	**4.5**
Average Daily Volume (sh)	**80,675**
Shares Outstanding (mil)	**28.1**
Market Capitalization ($mil)	**140**
Short Interest Ratio (days)	**15.0**
Institutional Ownership (%)	**74.1**
Insider Ownership (%)	**5.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$6.4 A	$6.0 A	$6.1 A	$2.5 A	$21.0 A
2021	$5.4 A	$4.5 A	$4.8 A	$12.4 A	$27.1 A
2022					$18.0 E
2023					$20.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$6.09 A	-$5.74 A	-$7.03 A	-$1.08 A	-$9.35 A
2021	-$0.59 A	-$0.68 A	-$0.80 A	-$0.42 A	-$2.49 A
2022					-$2.63 E
2023					-$2.22 E

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WHAT'S NEW

Full Year 2021 Operational and Financial Results

On March 16, 2022, SQZ Biotechnologies Company (NYSE: SQZ) reported 2021 financial and operational results in a press release concurrent with the filing of its Form 10-K.

Achievements for the fourth quarter ending December 31, 2021 and to-date include:

- DSMB recommendation to advance SQZ-PBMC-HPV-101 into combination study - October 2021
- Poster presentations for three oncology programs at SITC[1] - November 2021
- Acceptance by Roche Accelerator in China - December 2021
- Highest dose monotherapy cohort oral presentation at ESMO-IO[2] - December 2021
- John Maraganore, Ph.D. joins as Strategic Advisor - January 2022
- FDA clears IND for eAPC HPV in HPV16+ tumors - January 2022
- Publication of preclinical research on SQZ APC T cell activation - February 2022

Upcoming milestones include:

- Enhanced APC (eAPC) Phase I/II HPV COMMANDER trial launch - 1H:22
- APC monotherapy and initial combination data - 2H:22
- AAC HPV monotherapy interim data presentation - 2H:22
- eAPC HPV monotherapy interim data presentation - 2H:22
- AAC or eAPC IND-enabling activities for KRAS mutant solid tumors - 2H:22
- Celiac disease IND submission – 1H:23

SQZ generated revenues for 2021 of $27.1 million and incurred operating expenses of $95.9 million resulting in net loss of $68.7 million or ($2.49) per share.

For the year ended December 31, 2021, compared to the same period ending December 31, 2020:

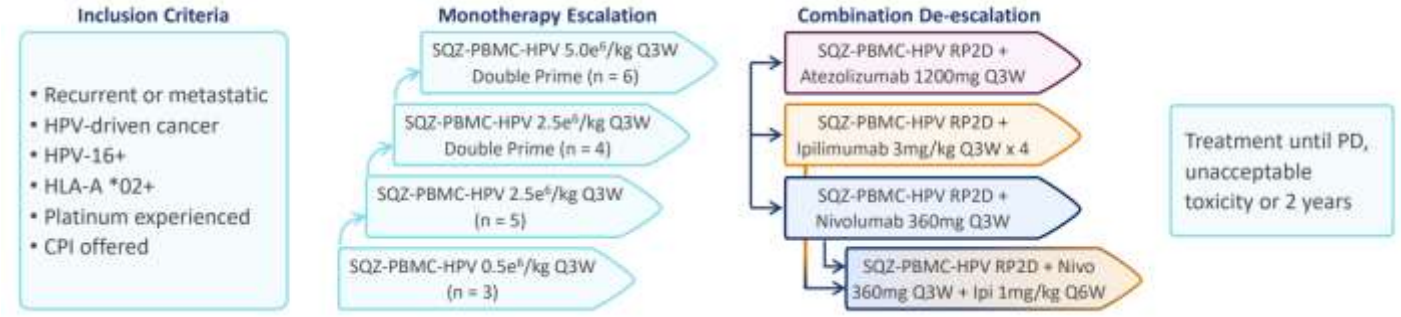
- Collaboration revenue totaled $27.1 million, up 29% from $21.0 million, on decrease in estimated incurred cost and entitlement to $3.0 million in milestone payments;
- Research and development expenses totaled $70.1 million, up 36% from $51.5 million on higher development and manufacturing costs associated with translating our product candidates into the clinic, as well as increased personnel-related costs to support pipeline progress;
- General and administrative expenses were $25.7 million, rising 25% from $20.5 million, due to higher personnel and other corporate-related costs, including stock-based compensation expense and other costs related to operating as a public company;
- Net loss was $68.7 million, compared to $50.5 million, or ($2.49) and ($9.35), respectively.

Cash and equivalents as of December 31, 2021 totaled $143.5 million. SQZ continues with no debt on its balance sheet. Cash burn for 2021 was $82.6 million, offset by financing cash flows of $55.9 million from its equity offering in February 2021.

[1] Society for Immunotherapy of Cancer
[2] European Society for Medical Oncology Immuno-Oncology

DSMB decision to advance with Checkpoint Inhibitors (CPI)
SQZ-APC-HPV is SQZ' lead candidate and is under investigation in Phase I clinical trials as a monotherapy, and in combination with other immuno-oncology agents atezolizumab, ipilimumab and nivolumab, for the treatment of HPV16+ advanced or metastatic solid tumors. The trial is enrolling patients with various HPV+ tumors who are HLA-A*02 positive and is a multicenter, open-label, dose-escalation and dose-expansion study. SQZ-PBMC-HPV is manufactured from patient PBMCs that have been squeezed with HPV16 oncoproteins E6 and E7 as antigens to present to and activate the patients' CD8+ T cells. Primary objectives of the trial are to assess safety and tolerability, and to determine maximum tolerated dose, if any, to guide future studies. Efficacy will also be evaluated as a secondary objective. Among the biomarkers being analyzed are HPV-specific T cells and associated cytokines, blood cytokine levels, CD8 T cell infiltration of the tumor, the tumor microenvironment and potential mechanisms of resistance. In June, SQZ presented initial results from the first three monotherapy cohorts at ASCO[3] Annual Meeting, discussed in our initiation. No treatment-related adverse events of grade 3 or higher were observed and all doses used in the trial were manufactured in under 24 hours with vein-to-vein time of one week. On October 26th, a press release disclosed that the Data and Safety Monitoring Board (DSMB) gave the go-ahead to proceed into combination trials with checkpoint inhibitors. This triggered a milestone payment from Roche.

Exhibit I - SQZ-PBMC-HPV-101 Trial Design[4]



ESMO-IO Preliminary Results and Webcast/Conference Call
SQZ hosted a webcast and conference call on December 9, 2021 to discuss updates to its SQZ-PBMC-HPV-101 program at ESMO[5] Immuno-Oncology Congress 2021. SQZ-PBMC-HPV-101 is the company's antigen presenting cell (APC) lead program. Jong Chul Park, MD presented, "Preliminary results from the first-in-human, dose-escalation study of a cell-based vaccine in HLA A*02+ patients with recurrent, locally advanced, or metastatic HPV16+ solid tumors." In contrast to cross-presentation, the basis for traditional prophylactic vaccines, Cell Squeeze is able to elicit a thousand-fold increase of T cell activation. Cross presentation favors creation of CD4+ helper cells and antibodies while Cell Squeeze prioritizes creation of CD8+ T cells via a different presentation mechanism of squeezing vs endocytosis. Additional detail on the publication can be found here, summarized in our previous report.

Poster Presentations for Three Oncology Programs at SITC
On November 12th, SQZ announced that it had presented three posters at the Society for Immunotherapy of Cancer (SITC) 36th Annual Meeting.

The titles of posters presented were:

- RBC-Derived, Activating Antigen Carriers (SQZ™ AACs) Prime Potent T Cell Responses and Drive Tumor Regression In Vivo
- SQZ™ eAPCs Generated from PBMCs by Delivery of Multiple mRNAs Encoding for Antigens, Costimulatory Proteins, and Engineered Cytokines
- Generating Enhanced Tumor Infiltrating Lymphocytes through Microfluidic Cell Squeezing

The first poster reviewed *in vivo* work in TC-1 tumor bearing mice (HPV16+) demonstrating synergy between SQZ AACs and cisplatin with median survival of mice increasing in all combination treatment cohorts compared to single agent cisplatin or AAC treatment. The second poster reported *in vitro* proof-of-concept work using mRNA to engineer SQZ eAPCs that stimulated CD8 T cell response across a range of HLA haplotypes. The third poster featured

[3] American Society of Clinical Oncology
[4] ESMO, December 2021. PowerPoint Presentation
[5] European Society for Medical Oncology

data generated from squeezing AgonOx CD8 TILs with IL-2 and IL-12 that confirmed high levels of membrane-bound cytokine expression *in vitro.* Squeezed TILs proliferated independent of exogenous IL-2. These cells also demonstrated increased tumor killing when matched with human melanoma cells.

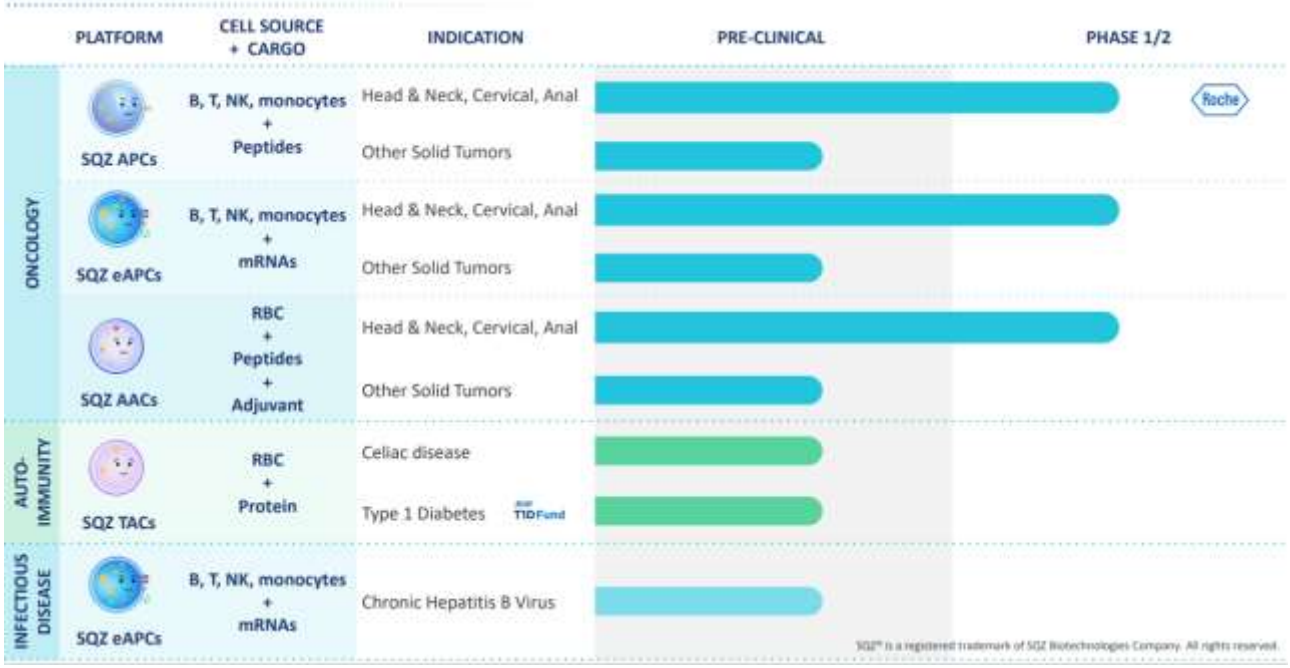
John Maraganore, Ph.D. Joins as Strategic Advisor
On January 6, 2022, SQZ announced that John Maraganore, Ph.D. joined SQZ as a Strategic Advisor. Dr. Maraganore served as the founding CEO and Director of Alnylam Pharmaceuticals, an RNA interference (RNAi)-focused company, from 2002 to 2021, where he built and led the company from early platform research on RNA interference through global approval and commercialization of the first three RNAi medicines. Prior to Alnylam, he served as an officer and a member of the management team for Millennium Pharmaceuticals and was responsible for the company's product franchises in oncology, and cardiovascular, inflammatory, and metabolic diseases. Before Millennium, he served as Director of Molecular Biology and Director of Market and Business Development at Biogen where he invented and led the discovery and development of ANGIOMAX (bivalirudin) for injection. Prior to Biogen, Dr. Maraganore was a scientist at ZymoGenetics, Inc. and the Upjohn Company. Dr. Maraganore received his Master of Science and Ph.D. in biochemistry and molecular biology at the University of Chicago. He is a Venture Partner at ARCH Venture Partners and a member of the board of directors of Agios Pharmaceuticals, Beam Therapeutics and the Biotechnology Industry Organization.

FDA Clears IND for SQZ-eAPC-HPV
On January 24, 2022, SQZ announced that the FDA had cleared its IND for SQZ-eAPC-HPV in HPV16+ solid tumors. SQZ' eAPCs are derived from patient peripheral blood mononuclear cells squeezed with target antigens and are enhanced with an mRNA payload that provides additional stimulatory signals to CD8 T cells, enabling more potent CD8 T cell responses. SQZ-eAPC-HPV is engineered with five different mRNA, encoding for multiple target antigens and immuno-stimulatory signals. The IND clearance will allow SQZ to proceed with its COMMANDER-001 Phase I/II clinical trial in HPV16+ solid tumor progressors. In preclinical models, SQZ eAPCs have been shown to generate robust CD8 T cell response against multiple antigens. COMMANDER-001 is evaluating SQZ-eAPC-HPV both as a monotherapy and in combination with pembrolizumab. The study consists of two parts. The first part will assess safety and tolerability of multiple doses of SQZ-eAPC-HPV in treatment-experienced patients following monotherapy dose escalation and dose de-escalation for the combination with pembrolizumab. The second will assess clinical response in less treatment-experienced patient populations.

Publication of Preclinical Research in SQZ APC
On February 1st, 2022, SQZ announced a publication entitled "Microfluidic Squeezing Enables MHC Class I Antigen Presentation by Diverse Immune Cells to Elicit CD8+ T Cell Responses with Antitumor Activity" in the February 15th Edition of *Journal of Immunology*, featuring comprehensive preclinical research on SQZ' ability to engineer a broader variety of immune cell types, namely T cells; B cells; NK cells; and monocytes, to drive MHC-I antigen presentation and subsequent CD8 T cell response across multiple antigens. CD8 T cells play a critical role in the immune response; however, a major hurdle for CD8 T cell activation has been presenting the desired antigen(s) to these T cells through the MHC-I pathway. In the publication, SQZ scientists and collaborators describe how this challenge is overcome through the delivery of antigens directly into the cytosol via microfluidic squeezing. In multiple *in vivo* studies, engineered B cells, T cells, or mixed PBMC[6] were all capable of activating the immune response across multiple antigens, where the immune responses conferred a prophylactic effect. The immune response was able to drive tumor regression and formed long-term memory against future tumor challenge. The protection correlated with infiltration of antigen-specific CD8 T cells. Finally, manufacturing scale viability of Cell Squeeze was confirmed demonstrating delivery up to a limit of two billion cells per minute and facilitating MHC class I presentation to CD8 T cells by human DCs, T cells, B cells and PBMCs.

[6] Peripheral blood mononuclear cells

Exhibit II - SQZ Pipeline[7]



Summary

SQZ reported 2021 financial and operational results. Highlights for the fourth quarter and to-date included progress on the SQZ-PBMC-HPV-101 trial, poster presentations at SITC and ESMO-IO, appointment of Dr. Maraganore as strategic advisor, FDA clearance of the SQZ-eAPC-HPV's IND, and publication of preclinical research on SQZ APC T cell activation.

In the financial realm, SQZ generated revenues for 2021 of $27.1 million and incurred operating expenses of $95.9 million resulting in net loss of ($68.7) million or ($2.49) per share. Cash and equivalents as of December 31, 2021 totaled $143.5 million. SQZ continues with no debt on its balance sheet. Cash burn for 2021 was $82.8 million, offset in part by financing cash flows of $55.9 million from its equity offering in February 2021. Based on our forecast, SQZ holds sufficient cash to support operations until mid-2023.

In 2022, SQZ anticipates enrollment and readout of its eAPC trial, reporting of data from its AAC monotherapy Phase I trial, potential submission of further INDs and expansion of the highest dose cohort in the AAC program. SQZ' portfolio, built on Cell Squeeze technology, offers treatments for multiple indications using a simple approach to engage the body's immune response. The most important near-term effort by SQZ is the launch of the enhanced APC Phase I/II COMMANDER trial in HPV which is slated to start in the next few months. The COMMANDER trial will investigate Squeeze's HPV therapy both as a monotherapy and in combination with checkpoint inhibitors. Results from SQZ' lead program provide further evidence that the APC platform stimulates an immune response in patients that have failed other lines of therapy. We maintain our target price of $30.00.

[7] SQZ March 2022 Corporate Presentation

PROJECTED FINANCIALS

SQZ Biotechnologies Company - Income Statement

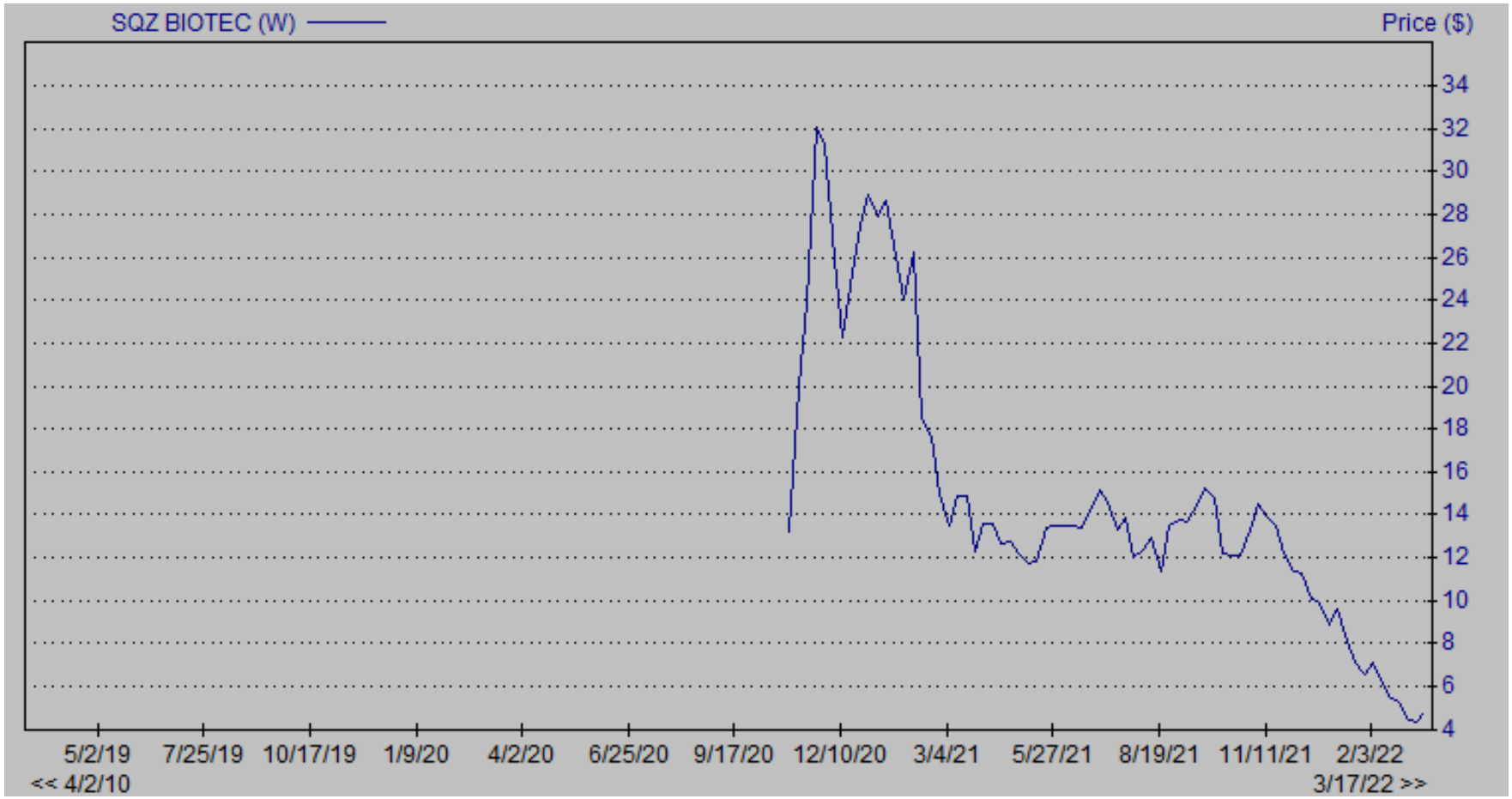
SQZ Biotechnologies Co.	2020 A	Q1 A	Q2 A	Q3 A	Q4 A	2021 A	2022 E	2023 E
Collaboration Revenue	$20,998	$5,454	$4,539	$4,755	$12,350	$27,098	$18,000	$20,000
Grant Revenue	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues ($US)	**$20,998**	**$5,454**	**$4,539**	**$4,755**	**$12,350**	**$27,098**	**$18,000**	**$20,000**
Research & Development	$51,545	$14,740	$17,682	$20,520	$17,206	$70,148	$67,250	$69,500
General & Administrative	$20,511	$6,120	$5,933	$6,691	$6,975	$25,719	$26,005	$28,240
Income from operations	($51,058)	($15,406)	($19,076)	($22,456)	($11,831)	($68,769)	($75,255)	($77,740)
Interest Income	$550	$9	$11	$8	$8	$36	$50	$50
Other Income	($13)	($2)	($5)	($2)	$1	($8)	$0	$0
Pre-Tax Income	($50,521)	($15,399)	($19,070)	($22,450)	($11,822)	($68,741)	($75,205)	($77,690)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($50,521)**	**($15,399)**	**($19,070)**	**($22,450)**	**($11,822)**	**($68,741)**	**($75,205)**	**($77,690)**
Reported EPS	**($9.35)**	**($0.59)**	**($0.68)**	**($0.80)**	**($0.42)**	**($2.49)**	**($2.63)**	**($2.22)**
Basic Shares Outstanding	5,402	26,264	27,920	28,050	28,082	27,579	28,628	35,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

SQZ Biotechnologies Company – Stock Price Chart[8]



[8] Source: Zacks Research System

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